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**42 CFR Part 405, et al.
Medicare Program; Changes to the
Hospital Inpatient Prospective Payment
Systems and Fiscal Year 2003 Rates; Final
Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, and 485

[CMS-1203-F]

RIN 0938-AL23

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare acute care hospital inpatient prospective payment systems for operating and capital costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this final rule, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are applicable to discharges occurring on or after October 1, 2002. We also are setting forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment systems.

In addition, we are setting forth changes to other hospital payment policies, which include policies governing: Payments to hospitals for the direct and indirect costs of graduate medical education; pass-through payments for the services of nonphysician anesthetists in some rural hospitals; clinical requirements for swing-bed services in critical access hospitals (CAHs); and requirements and responsibilities related to provider-based entities.

DATES: The provisions of this final rule are effective on October 1, 2002. This rule is a major rule as defined in 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), we are submitting a report to Congress on this rule on August 1, 2002.

FOR FURTHER INFORMATION CONTACT:

Stephen Phillips, (410) 786-4548, Operating Prospective Payments, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Hospital Geographic Reclassifications, and Postacute Transfer Issues.

Tzvi Hefter, (410) 786-4487, Capital Prospective Payment, Excluded

Hospitals, Graduate Medical Education, Provider-Based Entities, Critical Access Hospital (CAH). Stephen Heffler, (410) 786-1211, Hospital Market Basket Rebasing. Jeannie Miller, (410) 786-3164, Clinical Standards for CAHs.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Summary

1. Acute Care Hospital Inpatient Prospective Payment System

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of hospital inpatient stays under a prospective payment system. Under these prospective payment systems, Medicare payment for hospital inpatient

operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of an average standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located; and if the hospital is located in Alaska or Hawaii, the nonlabor share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital is recognized as serving a disproportionate share of low-income patients, it receives a percentage add-on payment for each case paid through the acute care hospital inpatient prospective payment system. This percentage varies, depending on several factors which include the percentage of low-income patients served. It is applied to the DRG-adjusted base payment rate, plus any outlier payments received.

If the hospital is an approved teaching hospital, it receives a percentage add-on payment for each case paid through the acute care hospital inpatient prospective payment system. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies that have been approved for special add-on payments. To qualify, the technologies must be shown to be a substantial clinical improvement over technologies otherwise available and that they would be inadequately paid otherwise (absent the add-on payments) under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any outlier payment due is added to the DRG-adjusted base payment rate.

Although payments to most hospitals under the acute care hospital inpatient prospective payment system are made on the basis of the standardized amounts, some categories of hospitals are paid the higher of a hospital-specific rate based on their costs in a base year (the higher of Federal fiscal year (FY) 1982, FY 1987, or FY 1996) or the prospective payment system rate based on the standardized amount. For example, sole community hospitals (SCHs) are the sole source of care in their areas, and Medicare-dependent, small rural hospitals (MDHs) are a major

source of care for Medicare beneficiaries in their areas. Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries (although MDHs receive only 50 percent of the difference between the prospective payment system rate and their hospital-specific rates, if the hospital-specific rate is higher than the prospective payment system rate).

The existing regulations governing payments to hospitals under the acute care hospital inpatient prospective payment system are located in 42 CFR Part 412, Subparts A through M.

2. Hospitals and Hospital Units Excluded from the Acute Care Hospital Inpatient Prospective Payment System

Under section 1886(d)(1)(B) of the Act, as amended, certain specialty hospitals and hospital units are excluded from the acute care hospital inpatient prospective payment system. These hospitals and units are: psychiatric hospitals and units; rehabilitation hospitals and units; long-term care hospitals; children's hospitals; and cancer hospitals. Various sections of the Balanced Budget Act of 1997 (Pub. L. 105-33), the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106-113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554) provide for the implementation of prospective payment systems for rehabilitation hospitals and units, psychiatric hospitals and units, and long-term care hospitals, as discussed below. Children's hospitals and cancer hospitals will continue to be paid on a cost-based reimbursement basis.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR Parts 412 and 413.

Under section 1886(j) of the Act, as amended, rehabilitation hospitals and units are being transitioned from a blend of reasonable cost-based reimbursement subject to a hospital-specific annual limit under section 1886(b) of the Act and Federal prospective payments for cost reporting periods beginning January 1, 2002 through September 30, 2002, to payment on a fully Federal prospective rate effective for cost reporting periods beginning on or after October 1, 2002 (66 FR 41316, August 7, 2001). The statute also provides that, for cost reporting periods beginning in FY 2003, inpatient rehabilitation facilities that are subject to the blend methodology may elect to receive the full prospective

payment instead of a blended payment. The existing regulations governing payment under the inpatient rehabilitation facility prospective payment system (for rehabilitation hospitals and units) are located in 42 CFR Part 412, Subpart P.

Under the broad authority conferred to the Secretary by section 123 of Public Law 106-113 and section 307(b) of Public Law 106-554, we are proposing to transition long-term care hospitals from payments based on reasonable cost-based reimbursement under section 1886(b) of the Act to fully Federal prospective rates during a 5-year period. For cost reporting periods beginning on or after October 1, 2006, we are proposing to pay long-term care hospitals under the fully Federal prospective payment rate. (See the proposed rule issued in the **Federal Register** on March 22, 2002 (67 FR 13416).) Under the proposed rule, during the transition, long-term care hospitals subject to the blend methodology would also be permitted to elect to be paid based on full Federal prospective rates. The final regulations governing payments under the long-term care hospital prospective payment system are under development and will be located in 42 CFR Part 412, Subpart O.

Sections 124(a) and (c) of Public Law 106-113 provide for the development of a per diem prospective payment system for payment for inpatient hospital services furnished by psychiatric hospitals and units under the Medicare program, effective for cost reporting periods beginning on or after October 1, 2002. This system must include an adequate patient classification system that reflects the differences in patient resource use and costs among these hospitals and must maintain budget neutrality. We are in the process of developing a proposed rule, to be followed by a final rule, to implement the prospective payment system for psychiatric hospitals and units.

3. Critical Access Hospitals

Under sections 1814, 1820, and 1834(g) of the Act, payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services on a reasonable cost basis. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR Parts 413 and 415.

4. Payments for Graduate Medical Education

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act; the amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year.

The existing regulations governing GME payments are located in 42 CFR Part 413.

B. Summary of the Provisions of the May 9, 2002 Proposed Rule

On May 9, 2002, we published a proposed rule in the **Federal Register** (67 FR 31404) that set forth proposed changes to the Medicare hospital inpatient prospective payment systems for operating costs and for capital-related costs in FY 2003. We also set forth proposed changes relating to payments for GME costs; payments to excluded hospitals and units; policies implementing the Emergency Medical Treatment and Active Labor Act (EMTALA); clinical requirements for swing beds in CAHs; and other hospital payment policy changes. These proposed changes would be effective for discharges occurring on or after October 1, 2002.

The following is a summary of the major changes that we proposed and the issues we addressed in the May 9, 2002 proposed rule:

1. Changes to the DRG Reclassifications and Recalibrations of Relative Weights

As required by section 1886(d)(4)(C) of the Act, we proposed annual adjustments to the DRG classifications and relative weights. Based on analyses of Medicare claims data, we proposed to establish a number of new DRGs and to make changes to the designation of diagnosis and procedure codes under other existing DRGs.

Among the proposed changes discussed were:

- Revisions of DRG 1 (Craniotomy Age >17 Except for Trauma) and DRG 2 (Craniotomy for Trauma Age >17) to reflect the current assignment of cases involving head trauma patients with other significant injuries to major diagnostic category (MDC) 24.

- Reconfiguration and retitling of existing DRG 14 (Specific Cerebrovascular Disorders Except Transient Ischemic Attack) and DRG 15

(Transient Ischemic Attack and Precerebral Occlusions) and creation of a new DRG 524 (Transient Ischemia).

- Creation of a new DRG 525 (Heart Assist System Implant) for heart assist devices.
- Reassignment of the diagnosis code for rheumatic heart failure with cardiac catheterization.
- Assignment of new, and reassignment of existing, cystic fibrosis principal diagnosis codes.
- Redesignation of a code for insertion of totally implantable vascular access device (VAD) as an operating room procedure.
- Changes in the DRG assignment for the bladder reconstruction procedure code.
- Changes in DRG and MDC assignments for numerous newborn and neonate diagnosis codes. (We note that, based on public comments received on the proposed rule, we are not making these changes in this final rule, as discussed in section II.B.6. of this preamble.)
- Changes in DRG assignment for cases of tracheostomy and continuous mechanical ventilation greater than 96 hours.
- We also discussed other DRG classification issues for which we did not propose changes. One of those was the new drug-eluting stent technology. We received many public comments suggesting higher payments would be needed in order to adequately compensate hospitals for the higher costs of this technology. Therefore, in this final rule, we are creating new DRG 525 (Percutaneous Cardiovascular Procedure with, Drug-Eluting Stent with AMI) and new DRG 527 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without AMI).

We also presented our analysis of applicants for add-on payments for high-cost new medical technologies. We have approved one new technology, the drug drotrecogin alfa (activated), trade name Xigris™, as a new technology eligible for add-on payments. Xigris™ is used to treat patients with severe sepsis.

2. Changes to the Hospital Wage Index

We proposed revisions to the wage index and the annual update of the wage data. Specific issues addressed in this section included the following:

- The FY 2003 wage index update, using FY 1999 wage data.
- Exclusion from the wage index of Part A physician wage costs that are teaching-related, as well as resident and Part A certified registered nurse anesthetist (CRNA) costs.

- Collection of data for contracted administrative and general, housekeeping, and dietary services.
- Revisions to the wage index based on hospital redesignations and reclassifications by the Medicare Geographic Classification Review Board (MGCRB).
- Requests for wage data corrections, including clarification of our policies on mid-year corrections.

3. Revision and Rebasings of the Hospital Market Basket

We proposed rebasing and revising the hospital market basket to be used in developing the FY 2003 update factor for the operating prospective payment rates and the excluded hospital rate-of-increase limits. We also set forth the data sources used to determine the revised market basket relative weights and choice of price proxies.

In the proposed rule, we also reestimated the labor-related share of the average standardized amount that is adjusted by the wage index. In response to public comments received recommending further evaluation of the methodology used to estimate the labor-related share, we are not proceeding with that reestimation in this final rule.

4. Other Decisions and Changes to the Prospective Payment System for Inpatient Operating and Graduate Medical Education Costs

We discussed several provisions of the regulations in 42 CFR Parts 412 and 413 and set forth certain proposed changes concerning the following:

- Options for expanding the postacute care transfer policy. Based on public comments received, we are not expanding the policy at this time.
- Clarification of the application of the statutory provisions on the calculation of hospital-specific rates for SCHs.
- Exclusion of certain limited-service specialty hospitals from the like hospital definition for purposes of granting SCH status. We proposed to set the threshold for determining a specialty hospital is not a like hospital at 3 percent service overlap between the SCH and the specialty hospital. In this final rule, in response to public comments, we are establishing that threshold at 8 percent.
- Technical change regarding additional payments for outlier cases.
- Proposed case-mix index values for FY 2003 for rural referral centers.
- Changes relating to the IME adjustment, including resident-to-bed ratio caps and counting beds. (We note that because of the need for a future comprehensive analysis on bed and

patient day counting policies, and our limited timeframe for preparing the FY 2003 final rule for the acute care hospital inpatient prospective payment systems for publication by the statutory deadline of August 1, 2002, we have decided to postpone finalizing the proposed changes and will address the comments in a separate document.)

- Clarification and codification of classification requirements for MDHs and intermediary evaluations of cost reports for these hospitals.
 - Changes to policies on pass-through payments for the costs of nonphysician anesthetists in some rural hospitals.
 - Clarification of policies relating to implementing 3-year reclassifications of hospitals and other policies related to hospital reclassification decisions made by the MGCRB.
 - Changes relating to payment for the direct costs of GME.
 - Changes relating to emergency medical conditions in hospital emergency departments under the EMTALA provisions. (We note that because of the number and nature of the public comments we received on these proposed changes and our limited timeframe for preparing the FY 2003 final rule for the acute care hospital inpatient prospective payment systems for publication by the statutory deadline of August 1, we have decided to postpone finalizing the proposed changes and will address the comments in a separate document.)
 - Criteria for, and responsibilities related to, payments for provider-based entities.
 - CMS-directed reopening of intermediary determinations and hearing decisions on provider reimbursements.
- We proposed to revise our methodology used to determine the fixed-loss cost threshold for outlier cases based on a 3-year average of the rates of change in hospitals' costs. We received many public comments opposing this change. In this proposed rule, we are using a 2-year average of the rate of change in charges to establish the threshold.

5. Prospective Payment System for Capital-Related Costs

We proposed payment requirements for capital-related costs effective October 1, 2002, which included:

- Capital-related costs for new hospitals.
- Additional payments for extraordinary circumstances.
- Restoration of the 2.1 percent reduction to the standard Federal capital prospective payment system rate.

- Clarification of the special exceptions payment policy.

6. Changes for Hospitals and Hospital Units Excluded From the Prospective Payment Systems

We discussed the following proposals concerning excluded hospitals and hospital units and CAHs:

- Payments for existing excluded hospitals and hospital units for FY 2003.
- Updated caps for new excluded hospitals and hospital units.
- Revision of criteria for exclusion of satellite facilities from the acute care hospital inpatient prospective payment system.
- The prospective payment systems for inpatient rehabilitation hospitals and units and long-term care hospitals.
- Changes in the advance notification period for CAHs electing the optional payment methodology.
- Removal of the requirement on CAHs to use a State resident assessment instrument (RAI) for patient assessments for swing-bed patients.

7. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits

In the Addendum to the May 9, 2002 proposed rule, we set forth proposed changes to the amounts and factors for determining the FY 2003 prospective payment rates for operating costs and capital-related costs. We also proposed threshold amounts for outlier cases. In addition, we proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2003 for hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system.

8. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected entities.

9. Report to Congress on the Update Factor for Hospitals Under the Prospective Payment System and Hospitals and Units Excluded From the Prospective Payment System

In Appendix B of the proposed rule, as required by section 1886(e)(3) of the Act, we set forth our report to Congress on our initial estimate of a recommended update factor for FY 2003 for payments to hospitals included in the acute care hospital inpatient prospective payment system, and hospitals excluded from this prospective payment system.

10. Recommendation of Update Factor for Hospital Inpatient Operating Costs

In Appendix C of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we included our recommendation of the appropriate percentage change for FY 2003 for the following:

- Large urban area and other area average standardized amounts (and hospital-specific rates applicable to SCHs and MDHs) for hospital inpatient services paid under the prospective payment system for operating costs.
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system.

11. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, the Medicare Payment Advisory Commission (MedPAC) is required to submit a report to Congress, not later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. This annual report makes recommendations concerning hospital inpatient payment policies. In the proposed rule, we discussed the MedPAC recommendations concerning hospital inpatient payment policies and presented our response to those recommendations. For further information relating specifically to the MedPAC March 1 report or to obtain a copy of the report, contact MedPAC at (202) 653-7220 or visit MedPAC's Web site at: www.medpac.gov.

C. Public Comments Received in Response to the May 9, 2002 Proposed Rule

We received approximately 1,196 timely items of correspondence containing multiple comments on the May 9, 2002 proposed rule. Summaries of the public comments and our responses to those comments are set forth below under the appropriate heading.

II. Changes to DRG Classifications and Relative Weights

A. Background

Under the acute care hospital inpatient prospective payment system, we pay for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual

hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Changes to the DRG classification system and the recalibration of the DRG weights for discharges occurring on or after October 1, 2002 are discussed below.

B. DRG Reclassification

1. General

Cases are classified into DRGs for payment under the acute care hospital inpatient prospective payment system based on the principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay, as well as age, sex, and discharge status of the patient. The diagnosis and procedure information is reported by the hospital using codes from the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).

For FY 2003, cases are assigned to one of 510 DRGs in 25 major diagnostic categories (MDCs). Most MDCs are based on a particular organ system of the body. For example, MDC 6 is Diseases and Disorders of the Digestive System. However, some MDCs are not constructed on this basis because they involve multiple organ systems (for example, MDC 22 (Burns)).

In general, cases are assigned to an MDC based on the patients' principal diagnosis before assignment to a DRG. However, for FY 2003, there are eight DRGs to which cases are directly assigned on the basis of ICD-9-CM procedure codes. These are the DRGs for heart, liver, bone marrow, lung transplants, simultaneous pancreas/kidney, and pancreas transplants (DRGs 103, 480, 481, 495, 512, and 513, respectively) and the two DRGs for tracheostomies (DRGs 482 and 483). Cases are assigned to these DRGs before classification to an MDC.

Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are based on a

hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures, by resource intensity. Medical DRGs generally are differentiated on the basis of diagnosis and age. Some surgical and medical DRGs are further differentiated based on the presence or absence of complications or comorbidities (CC).

Generally, nonsurgical procedures and minor surgical procedures not usually performed in an operating room are not treated as O.R. procedures. However, there are a few non-O.R. procedures that do affect DRG assignment for certain principal diagnoses, such as extracorporeal shock wave lithotripsy for patients with a principal diagnosis of urinary stones.

Patients' diagnosis, procedure, discharge status, and demographic information is fed into the Medicare claims processing systems and subjected to a series of automated screens called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before classification into a DRG.

After screening through the MCE and any further development of the claims, cases are classified into the appropriate DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into a DRG on the basis of the diagnosis and procedure codes and, for a limited number of DRGs, demographic information (that is, sex, age, and discharge status). The GROUPER is used both to classify current cases for purposes of determining payment and to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights.

The records for all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights. However, in the July 30, 1999 final rule (64 FR 41500), we discussed a process for considering non-MedPAR data in the recalibration process. In order for the use of particular data to be feasible, we must have sufficient time to evaluate and test the data. The time necessary to do so depends upon the nature and quality of the data submitted. Generally, however, a significant sample of the data should be submitted by mid-October, so that we can test the data and make a preliminary assessment as to the feasibility of using the data. Subsequently, a complete database should be submitted no later than December 1 for consideration in

conjunction with next year's proposed rule.

We proposed numerous changes to the DRG classification system for FY 2003. The proposed changes, the public comments we received concerning them, and the final DRG changes and the methodology used to recalibrate the DRG weights are set forth below. Unless otherwise noted, the changes we are implementing will be effective in the revised GROUPER software (Version 20.0) to be implemented for discharges on or after October 1, 2002. Also, unless otherwise noted, we are relying on the DRG data analysis in the proposed rule for the changes discussed below.

2. MDC 1 (Diseases and Disorders of the Nervous System)

a. Revisions of DRGs 1 and 2

Currently, adult craniotomy patients are assigned to either DRG 1 (Craniotomy Age >17 Except for Trauma) or DRG 2 (Craniotomy for Trauma Age >17). The trauma distinction recognizes that head trauma patients requiring a craniotomy often have multiple injuries affecting other body parts. However, we note that the structure of these DRGs predates the creation in FY 1991 of MDC 24 (Multiple Significant Trauma). The creation of MDC 24 resulted in head trauma patients with other significant injuries being assigned to MDC 24 and removed from DRG 2. In FY 1990, there was a 16-percent difference in the DRG weights for DRG 1 and DRG 2. In FY 1992, after the creation of MDC 24, the percentage difference in the DRG weights for DRG 1 and DRG 2 had declined to 1.2 percent. The FY 2002 payment weight for DRG 1 is 3.2713 and for DRG 2 is 3.3874, a 3.5 percent difference.

For FY 2003, we reevaluated the GROUPER logic for DRGs 1 and 2 by combining the patients assigned to these DRGs and examining the impact of other patient attributes on patient charges. The presence or absence of a CC was found to have a substantial impact on patient charges.

Cases in DRGs 1 and 2	Number of patients	Average charges
With CC	19,012	\$49,659
Without CC	9,618	26,824

Thus, there is an 85.1 percent difference in average charges for the groups with and without CC for the combined DRGs 1 and 2. On this basis, we proposed to redefine and retitle DRGs 1 and 2 as follows: DRG 1 (Craniotomy Age >17 with CC); and

DRG 2 (Craniotomy Age >17 without CC).

Comment: Nine commenters addressed this proposal. Three of the commenters supported the proposal. One commenter was concerned about the significant redefinition of DRGs to the extent that longitudinal DRG data analysis would be seriously comprised. This commenter recommended that we consider creating new DRGs when significant changes to the structure of existing DRGs are necessary in order to preserve the core definition of the existing DRGs for data analysis purposes. The commenter believed that this proposed revision would significantly alter the definition of these DRGs.

Response: We appreciate the support of the commenters for our position on this issue. In response to the commenter's concern that this revision would significantly alter the definition of these DRGs, thus affecting longitudinal DRG data analysis, our practice in the past has been to alter current DRGs to account for better clinical coherence as well as similar patterns of resource intensity. For example, last year we removed defibrillator cases from DRGs 104 and 105 to make these DRGs and the new DRGs 514 and 515 that were created for defibrillators, more homogenous in terms of patient characteristics and resource consumption.

Currently, the DRGs are generally ordered by MDC, which gives the DRGs a logical structure. Adding new DRGs sequentially at the end of the existing DRGs disturbs that order. However, because there is not a perfect solution to this problem, we will take the commenter's concerns into consideration as we proceed with future DRG revisions.

Longitudinal data analysis can be performed by mapping prior year's data with the current Medicare GROUPER. A conversion table is available for this purpose through the National Center for Health Statistics' website: <http://www.cdc.gov/nchs/icd9.htm> or may be purchased from the American Hospital Association (1-800-261-6246).

Comment: A commenter from a manufacturer of an implantable intracranial neurostimulator device used in the treatment of Parkinson's disease and essential tremor recommended that we revise the proposed revisions to DRGs 1 and 2 so that all deep brain stimulation procedures, such as intracranial neurostimulators for Parkinson's disease, are paid under proposed DRG 1. The commenter stated that, based on its review of FY 2000 MedPAR data,

approximately 75 percent of these cases would be assigned to proposed DRG 2 (and subject to an approximate 40-percent payment reduction under the proposed rule).

Response: Our proposed modification was based on FY 2001 MedPAR data. DRGs 1 and 2 included many different procedures with a range of costs associated with these procedures. Our analysis indicated a substantial cost differential between patients with CCs and patients without CCs, and the current DRGs 1 and 2 do not reflect this difference. We believe that the revision we proposed will improve the payment accuracy for cases in these DRGs. The prospective payment system is an average-based payment methodology under which losses that may be incurred for specific procedures or classes of patients are offset by payment gains from other procedures or classes of patients.

In our analysis, we found 847 cases in which an implantation of intracranial neurostimulator procedures was reported. The majority of these cases were being assigned to DRG 2 with average standardized charges of approximately \$37,546. These charges are higher than the overall average standardized charges for all cases within DRG 2. However, this group of cases represents a small subset of all of the cases that are assigned to DRG 2. As noted above, we believe our proposed changes represent an overall improvement in payment accuracy for the over 40,000 cases assigned to these two DRGs.

Comment: Three commenters expressed concern with the proposed restructuring of DRGs 1 and 2 as it pertains to the open or endovascular treatment of ruptured or nonruptured aneurysms and arteriovenous malformation.

One commenter submitted data showing the average charges for ruptured aneurysm cases at \$34,794 (and in some cases, \$52,568), which are more than the average charges for DRG 1, and lengths of stay that are significantly higher than those for the proposed DRG 1. Another commenter assumed that treatment for ruptured aneurysms will remain in the revised DRG 1, and stated that our proposal to reduce the cost variance of these DRGs is a good beginning. However, according to the commenter, this proposed change does not go far enough because it will continue to underpay these extremely resource intensive cases. The commenter recommended that these cases be assigned to a different DRG (DRG 484 (Craniotomy for Multiple Significant Trauma) was suggested) or

that a new DRG be created for these cases.

With respect to the treatment of nonruptured aneurysms, the commenters noted that we did not specify whether these cases would be assigned to DRG 1 or 2 and urged that these cases be assigned to DRG 1. The commenter noted that nonruptured interventional aneurysm cases are complex, and patients spend an average of 4.2 days in intensive care.

Response: In these cases, the patients' principal diagnosis would probably be the aneurysm. It is the secondary diagnosis or secondary condition that may be classified as a CC. Under the proposed changes, cases would be assigned to DRG 1 on the basis of a complication that occurred during the hospital stay or a comorbidity that existed at the time of admission or developed during the course of hospitalization. We found in our analysis that the majority of ruptured aneurysm cases and over half of craniotomy procedures in nonruptured aneurysm cases were being assigned to DRG 1, where charges for these cases were similar to the average for all cases in this DRG. The remaining nonruptured aneurysm cases were assigned to DRG 2 (\$33,144 compared to \$52,254). Our analysis did show the average standardized charges for the ruptured aneurysm to be \$109,698, which is higher than the overall average charges of all cases within DRG 1. However, we point out, as noted by the commenter, these cases actually do receive higher payments under the changes we proposed.

Currently, DRG 484 includes complex, multiple significant trauma cases; that is, patients with a principal diagnosis of trauma and at least two significant trauma diagnosis codes (either as principal or secondaries) from different body site categories. While the intensity of treatment for aneurysms and arteriovenous malformations is significant, we do not believe aneurysm and arteriovenous malformation cases are clinically similar to other cases currently assigned to DRG 484.

Comment: One commenter stated that procedures involving implantation of a chemotherapeutic agent into the brain will be underpaid, causing hospitals to further limit use of this technology. The commenter provided data based on 24 patients being treated with this procedure and concluded that the hospital claims data did not reflect the true hospital cost for this product. The commenter stated that the average cost for this procedure is approximately \$26,113. The commenter believed that these cases would be assigned to DRG

2 with an estimated payment of approximately \$13,225.

Response: Procedure code 00.10 (Implantation of a chemotherapeutic agent) will be effective October 1, 2002, that will enable specific identification of these procedures. At this point, there are limited data available to assess the payment implications of our proposed change on this procedure. As noted above, cases that remain in DRG 1 would receive higher payments as a result of this change. Further, we would expect hospitals to generally be able to offset payment losses associated with a procedure that is used only rarely with payment gains associated with the higher payments for higher volume cases in DRG 1. Also, a low markup associated with one device or procedure is often offset by relatively higher markups associated with another device or procedure, leading to higher relative weights, and thus higher payments, for the latter device or procedure.

We believe that our proposal is appropriate according to currently available data. Therefore, we are adopting as final our proposal to redefine and retitle DRGs 1 and 2 as follows: DRG 1 (Craniotomy Age >17 with CC); and DRG 2 (Craniotomy Age >17 without CC).

b. Revisions of DRGs 14 and 15

To assess the appropriate classification of patients with stroke symptoms, we evaluated the assignment of cases to DRG 14 (Specific Cerebrovascular Disorders Except Transient Ischemic Attack (TIA) and DRG 15 (Transient Ischemic Attack and Precerebral Occlusions). Our data review indicated that the cases in DRGs 14 and 15 fell into three discrete groups. The first group included cases in which the patients were very sick, with severe intracranial lesions or subarachnoid hemorrhage and severe consequences. The second group included cases in which patients had not suffered a debilitating stroke but instead may have experienced a transient ischemic attack. The patients in the second group had one half of the average length of stay in the hospital as the first group. The third group of cases included patients who appeared to suffer strokes with minor consequences, as well as those having occluded vessels without having a full-blown stroke.

We found that patients who have intracranial hemorrhage and patients who have infarction are similar in severity. We proposed to continue to group patients with intracranial hemorrhage and infarction together. These types of cases are different from patients with, for example, an occlusive

carotid artery without infarction. In this latter group of cases, patients are not as severely ill because they typically have lesser degrees of functional status deficits.

Our analysis indicates that we can improve the clinical and resource cohesiveness of DRGs 14 and 15 by reassigning several specific ICD-9-CM codes. For example, code 436 (Acute, but ill-defined, cerebrovascular disease) is a non-specific code and contains patients with a wide range of deficits

and anatomic problems. Our data show that these cases consume fewer resources and have shorter lengths of stay than other cases in DRG 14. Therefore, we proposed to remove code 436 from DRG 14 and reassign it to DRG 15. We also proposed to create a third new DRG that would help further differentiate cases currently assigned to DRGs 14 and 15. The proposed revised and new DRG titles were as follows: DRG 14 (Intracranial Hemorrhage and Stroke with Infarction); DRG 15

(Nonspecific Cerebrovascular Accident and Precerebral Occlusion without Infarction) (a corrected title from the one in the proposed rule); and DRG 524 (Transient Ischemia).

The following table represents a reconfiguration of DRGs 14 and 15 and the creation of a new DRG 524 reflecting these three categorizations (based on more recent data than that used in the proposed rule):

DRG and Title	Number of cases	Average length of stay (days)	Average charge
Revised DRG 14 (Intracranial Hemorrhage and Stroke with Infarction)	236,067	6.1	\$15,643
Revised DRG 15 (Nonspecific Cerebrovascular Accident and Precerebral Occlusion without Infarction)	101,726	4.9	11,595
New DRG 524 (Transient Ischemia)	136,857	3.4	8,633

The reconfiguration of DRGs 14 and 15 results in the following codes being designated as principal diagnosis codes in revised DRG 14:

- 430, Subarachnoid hemorrhage.
- 431, Intracerebral hemorrhage.
- 432.0, Nontraumatic extradural hemorrhage.
- 432.1, Subdural hemorrhage.
- 432.9, Unspecified intracranial hemorrhage.
- 433.01, Occlusion and stenosis of basilar artery, with cerebral infarction.
- 433.11, Occlusion and stenosis of carotid artery, with cerebral infarction.
- 433.21, Occlusion and stenosis of vertebral artery, with cerebral infarction.
- 433.31, Occlusion and stenosis of multiple and bilateral arteries, with cerebral infarction.
- 433.81, Occlusion and stenosis of other specified precerebral artery, with cerebral infarction.
- 433.91, Occlusion and stenosis of unspecified precerebral artery, with cerebral infarction.
- 434.01, Cerebral thrombosis with cerebral infarction.
- 434.11, Cerebral embolism with cerebral infarction.
- 434.91, Cerebral artery occlusion, unspecified, with cerebral infarction.

We proposed that the following two codes be moved from DRG 14 to DRG 34 (Other Disorders of Nervous System with CC) and DRG 35 (Other Disorders of Nervous System without CC): Code 437.3 (Cerebral aneurysm, nonruptured) and Code 784.3 (Aphasia). These codes do not represent acute conditions. Aphasia, for example, could result from a cerebral infarction, but if it does, the infarction should be correctly coded as the principal diagnosis.

We proposed redefining DRG 15 so that it contains the following principal diagnosis codes:

- 433.00, Occlusion and stenosis of basilar artery, without mention of cerebral infarction.
- 433.10, Occlusion and stenosis of carotid artery, without mention of cerebral infarction.
- 433.20, Occlusion and stenosis of vertebral artery, without mention of cerebral infarction.
- 433.30, Occlusion and stenosis of multiple and bilateral arteries, without mention of cerebral infarction.
- 433.80, Occlusion and stenosis of other specified precerebral artery, without mention of cerebral infarction.
- 433.90, Occlusion and stenosis of unspecified precerebral artery, without mention of cerebral infarction.
- 434.00, Cerebral thrombosis without mention of cerebral infarction.
- 434.10, Cerebral embolism without mention of cerebral infarction.
- 434.90, Cerebral artery occlusion, unspecified, without mention of cerebral infarction.
- 436, Acute, but ill-defined, cerebrovascular disease.

We proposed to remove the following codes from the existing DRG 15 and place them in the proposed newly created DRG 524:

- 435.0, Basilar artery syndrome.
- 435.1, Vertebral artery syndrome.
- 435.2, Subclavian steal syndrome.
- 435.3, Vertebrobasilar artery syndrome.
- 435.8, Other specified transient cerebral ischemias.
- 435.9, Unspecified transient cerebral ischemia.

We proposed to move code 437.1 (Other generalized ischemic cerebrovascular disease) from DRG 16 (Nonspecific Cerebrovascular Disorders with CC) and DRG 17 (Nonspecific Cerebrovascular Disorders without CC)

and add it to the proposed new DRG 524. This proposed change represented a modification to improve clinical coherence and seems to be a logical change for the construction of the proposed new DRG 524.

Comment: Several commenters opposed the movement of code 436 from DRG 14 into DRG 15. One commenter stated that the change is not supported in either the ICD-9-CM coding manual or the *Coding Clinic* for ICD-9-CM. The commenter noted that an inclusion note under code 436 identified this code as a diagnosis code for a stroke patient with cerebral infarctions. In addition, the commenter cited the *Coding Clinic*, Fourth Quarter, 1993 (pages 38 and 39), as including the term “cerebral infarction” following the term “stroke”, which indicated to the commenter that these terms are synonymous. The commenter recommended that, prior to making any changes, CMS work with the ICD-9-CM Coordination and Maintenance Committee to revise the ICD-9-CM tabular section to correct this inconsistency.

Response: We agree with the commenter that the ICD-9-CM code 436 does, in fact, describe a stroke. However, the code is nonspecific as to the nature of a stroke. In addition, data on cases containing code 436 that were reported in our MedPAR file indicated that these types of cases have a shorter length of stay and lower hospital charges associated with them. Our revised title of DRG 15 reflects our recognition of code 436 as describing a stroke; that is, we are changing the title of DRG 15 to “Nonspecific Cerebrovascular Accident and Precerebral Occlusion without Infarction.” With regard to the revision

of the ICD-9-CM diagnosis tabular section describing code 436, we understand that the National Center for Health Statistics (NCHS) plans to address this issue at the December 4th and 5th, 2003 meeting of the ICD-9-CM Coordination and Maintenance Committee. While we agree with NCHS' plan to examine this issue, we are not delaying these DRG changes while waiting for modifications to this section of the coding manual.

Comment: Two commenters opposed any changes in DRGs 14 and 15 until better data become available. One of these commenters noted that moving approximately 80,000 cases from a higher paying DRG to a lower paying DRG will significantly impact many hospital's financial status.

Both commenters opposed moving code 436 from DRG 14 into DRG 15, noting that code 436 is a common code for stroke or cerebrovascular accident when the physician does not specify whether the stroke is an intracranial hemorrhage or cerebral infarction. The commenters noted that performance of diagnostic imaging may add specificity to determine which artery was involved, thus allowing more specific coding to occur. However, it may not change the course of treatment for the stroke. In addition, the commenters stated that, in some cases, it is ill-advised to subject the patient to further testing to make this determination. Further, in some cases, the tests may be inconclusive but in most cases the course of treatment would not be changed.

One commenter indicated that there is probably inconsistency among coders in the use of the more specific 5-digit codes for "with cerebral infarction" for categories 433 (Occlusion and stenosis of precerebral arteries) and 434 (Occlusion of cerebral arteries) due to variable interpretations of coding instructions. The commenter noted that there are currently efforts to provide clarification regarding the proper use of these 5-digit codes.

Response: We recognize that some of the diagnostic codes in section 430 through 437 of ICD-9-CM may be more specific than the diagnostic documentation in the medical record, which may make it difficult to precisely code cerebrovascular disease. We also recognize that code 436 may be a catchall code when more specific information on the patient's condition is not available in the record. Further, it is possible that other less severe cases are being labeled "stroke," absent more thorough testing or workup. However, our proposed changes to DRGs 14 and 15 were based on actual MedPAR data from FY 2001. As demonstrated above,

there is a clear demarcation between average charges and lengths of stay across the two revised DRGs and one new DRG. Further, payment for many cases is higher after these changes than it was previously. For FY 2003, the DRG relative weights for DRGs 14 and 15 were 1.1655 and 0.7349, respectively. The proposed FY 2003 relative weights for DRGs 14, 15 and 524 were 1.2742, 0.9844, and 0.7236. Therefore, cases remaining in DRG 14 would receive higher payments as a result of moving less expensive cases into DRG 15 or 524. Similarly, cases remaining in DRG 15 would receive much higher payments than they had previously.

We believe these changes improve the clinical and resource cohesiveness of the DRGs for these cases. We acknowledge the concerns expressed by the commenters that code 436 may frequently be used in lieu of more specific codes that require further tests even though the cases are as severely ill as those with more specific diagnosis indicated on the bill. However, this is not borne out by the data.

To the prospect of more available data in the future, we note that changes to codes in the related section of the ICD-9-CM coding book have been in place since 1993. We believe that 9 years is sufficient time to clarify the coding issues and to adequately train both the coding and medical staffs regarding documentation of cerebrovascular disease.

Comment: One commenter opposed the movement of code 437.1 to new DRG 524, noting that conditions classified to this code are generally chronic or long term in nature, not transient.

Response: The titles of DRGs are not intended to uniquely identify each case within the DRG, but to logically group cases that globally have similar characteristics in terms of clinical requirements and resources utilized. We proposed the movement of code 437.1 from DRGs 16 and 17 in order to improve the clinical coherence of DRGs 16 and 17, and the new DRG 524; we believe this change accomplishes that. Therefore, we are adopting the proposed change as final.

Comment: One commenter supported the movement of codes 437.3 and 784.3 from DRG 14 to DRGs 34 and 35.

Response: We appreciate the commenter's support. Accordingly, we are adopting the proposed change to move codes 437.3 and 784.3 to DRGs 34 and 35, as final.

We are adopting as final the proposed changes to DRGs 14 and 15 and the creation of new DRG 524 without modifications. We will continue to

monitor these DRGs for shifts in resource consumption and validity of DRG assignment and will specifically monitor code 436 for appropriate placement in DRG 15. We support the concept of clarification of the coding guidelines in this section of ICD-9-CM and will also monitor these DRGs when the guidelines are updated.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Heart Assist Systems

Heart failure is typically caused by persistent high blood pressure (hypertension), heart attack, valve disease, other forms of heart disease, or birth defects. It is a chronic condition in which the lower chambers of the heart (ventricles) cannot pump sufficient amounts of blood to the body. This causes the organs of the body to progressively fail, resulting in numerous medical complications and frequently death. DRG 127 (Heart Failure and Shock), to which heart failure cases are assigned, is the single most common DRG in the Medicare population, and represents the medical, not surgical, treatment options for this group of patients.

In many cases, heart transplantation would be the treatment of choice. However, the low number of donor hearts limits this treatment option. Circulatory support devices, also known as heart assist systems or left ventricular assist devices (LVADs), offer a surgical alternative for end-stage heart failure patients. This type of device is often implanted near a patient's native heart and assumes the pumping function of the weakened heart's left ventricle. Studies are currently underway to evaluate LVADs as permanent support for end-stage heart failure patients.

We have reviewed the payment and DRG assignment of this type of device in the past. Originally, these cases were assigned to DRG 110 (Major Cardiovascular Procedures with CC) and DRG 111 (Major Cardiovascular Procedures without CC) in the September 1, 1994 final rule (59 FR 45345). A more specific procedure code, 37.66 (Implant of an implantable, pulsatile heart assist system) was made effective for use with hospital discharges occurring on or after October 1, 1995. In the August 29, 1997 final rule (62 FR 45973), we reassigned these cases to DRG 108 (Other Cardiothoracic Procedures), because it was the most clinically similar DRG with the best match in resource consumption according to our data. In the July 31, 1998 final rule (63 FR 40956), we again reviewed our data and discovered that

the charges for implantation of an LVAD were increasing at a greater rate than the average charges for DRG 108. The length of stay for cases with code 37.66 was approximately 32 days, or three times as long as all other DRG 108 cases.

Therefore, we decided to move LVAD cases from DRG 108 to DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization) and DRG 105 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization). We continued to review our data and discuss this topic in the FY 1999 and FY 2000 annual final rules: July 30, 1999 (64 FR 41498) and August 1, 2000 (65 FR 47058).

In the August 1, 2001 final rule (66 FR 39838), we remodeled MDC 5 to add five new DRGs. We also added procedure codes 37.62 (Implant of other heart assist system), 37.63 (Replacement and repair of heart assist system), and 37.65 (Implant of an external, pulsatile heart assist system) to DRGs 104 and 105. We removed defibrillator cases from DRGs 104 and 105 and assigned them to DRG 514 (Cardiac Defibrillator Implant with Cardiac Catheterization) and DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization) to make these DRGs more clinically coherent. This also increased the relative weights for DRGs 104 and 105, as the defibrillator cases had lower average charges than other cases in those two DRGs.

In the FY 2001 MedPAR data file, we found 185 LVAD cases in DRG 104 and 90 cases in DRG 105, for a total of 275 cases. These cases represent 1.3 percent of the total cases in DRG 104, and approximately 0.5 percent of the total cases in DRG 105. However, the average charges for these cases are approximately \$36,000 and \$85,000 higher than the average charges for cases in DRGs 104 and 105, respectively.

This situation presents a dilemma, in that the technology has been available since 1995 and is gradually increasing in utilization, while LVAD cases remain a small part of the total cases in these two DRGs. In fact, removing LVAD cases from the calculation of the average charge changes the average by only -0.4 percent and -0.5 percent for DRGs 104 and 105, respectively. Therefore, despite the dramatically higher average charges for LVADs compared to the DRG averages, the relative volume is insufficient to affect the DRG average charges to any great degree.

Therefore, we proposed to create a new DRG 525 (Heart Assist System Implant), which would contain these

cases. The FY 2003 relative weight for the new DRG 525 is 11.6479.

As discussed below, the comments we received supported this change.

Therefore, we are creating new DRG 525, which consists of any principal diagnosis in MDC 5, plus one of the following surgical procedures:

- 37.62, Implant of other heart assist system
- 37.63, Replacement and repair of heart assist system
- 37.65, Implant of an external, pulsatile heart assist system
- 37.66, Implant of an implantable, pulsatile heart assist system

Cases in which a subsequent heart transplant occurs during the hospitalization episode will continue to be assigned to DRG 103 (Heart Transplant) because cases involving procedure codes 336 (Combined heart/lung transplant) and 375 (Heart transplant) are assigned to DRG 103, regardless of other codes included on the bill.

We reiterate a discussion we included in the August 1, 2000 final rule (65 FR 47058) regarding placement of code 37.66 in the MCE screening software as a noncovered procedure. The default designation for that code will continue to be "noncovered" because of the stringent conditions that must be met by hospitals in order to receive payment for implantation of the device.

Section 65-15 of the Medicare Coverage Issues Manual (Artificial Hearts and Relative Devices) provides the national coverage determination regarding Medicare coverage of these devices. This section may be accessed online at www.hcfa.gov/pubforms/06_cim/ci00.htm.

Comment: Several commenters supported the proposed creation of a new DRG 525 for patients receiving implanted heart assist systems. One commenter stated that the creation of a new DRG 525 would be more sensitive to the patient population, more accurate in statistical analysis and data reports, and more responsive to changes in LVAD charges and utilization patterns.

Other commenters suggested that the payment amount still understates the reasonable cost of LVAD implantation. One commenter provided analysis that purported to show that the net payment effect of this change is insignificant due to the increase in the outlier threshold as discussed in the proposed rule (and in the Addendum to this final rule).

Another commenter stated that this new DRG results in payment that does not even compensate for the costs to the hospital of the device itself. The commenter noted that current payment levels for LVADs do not take into

account the equipment required for discharge, that is, both disposable and durable medical equipment.

Some of the commenters recommended that we consider allowing LVADs to qualify for a new technology add-on payment in addition to establishing a new DRG specific to this technology.

Response: Regarding the commenter's analysis of the net payment effect of the proposed new DRG 525, the increase in the outlier threshold is not related to the creation of the new DRG 525. As discussed in detail in the Addendum, the FY 2002 outlier threshold was set at a point that resulted in excessive outlier payments. The commenter's analysis compared payments if these cases remained in DRGs 104 and 105 and received outlier payments in accordance with the lower FY 2002 outlier threshold to payments under the new DRG 525 using the proposed outlier threshold. Therefore, the commenter's analysis does not accurately represent payments under the DRGs. The correct analysis is to compare payments under DRGs 104 and 105 with payments under the new DRG 525, absent outlier payments, which results in an increase in payments of over 40 percent per case. Since cases qualify for outlier payments on the basis of a constant fixed-dollar loss threshold and receive payments equal to 80 percent of costs above the threshold, the 40-percent differential in payments is not affected by outlier payments.

With regard to the commenters' indication that the payment under the new DRG 525 is insufficient, we note that the DRG relative weights are based on charge data for actual LVAD cases in the Medicare discharge database, using the most recent information available (the FY 2001 MedPAR file). (Section I.I.C. of this final rule contains a complete discussion of this methodology.)

With regard to the commenter's suggestion that LVADs be eligible for add-on payments for new technology, we point out that our criteria require that the mean charges of the cases involving a new technology exceed a threshold of one standard deviation beyond the mean charge for all cases in the DRG. Since DRG 525 is specific to heart assist systems, the mean charge of the cases involving the new technology is the same as the mean charge for all cases in the DRG. Also, this technology does not meet our criteria to be considered new (see discussion at section II.D. below).

Finally, with regard to the concept that the DRG payment for LVAD should take into account disposable and

durable medical equipment after discharge, we point out that the Medicare Part A inpatient hospital payment is distinct from the Medicare Part B outpatient payments.

Comment: One commenter stated if LVAD implantation is approved for patients who are not heart transplant patients, the payment is likely to still be too low, as it is anticipated that these patients comprise a generally sicker population. The commenter suggested that we direct hospitals to bill uniformly for LVAD devices via the designated ICD-9-CM procedure codes that will classify into DRG 525.

Response: As we noted in the proposed rule, we understand that studies are currently underway to evaluate LVADs as permanent support for end-stage heart failure patients. However, at this time, these applications are only on a trial basis. Further, in the absence of specific data demonstrating additional costs associated with expanded uses of LVADs beyond bridge-to-transplant patients, we do not take anticipated higher costs into account in the DRG relative weight calculation. However, we will continue to monitor new DRG 525 as new developments occur in the approved uses of LVAD technology to ensure appropriate classification and payment of these cases.

With respect to the comment that we should provide further guidance on the correct ICD-9-CM coding procedures for LVADs, as explained above and in the proposed rule, cases with any principal diagnosis in MDC 5 reporting code 37.62, 37.63, 37.65, or 37.66 will be assigned to DRG 525 (in the absence of a transplant). Further information regarding the use of these codes may be obtained by referring to a relevant article from the *Coding Clinic*, Fourth Quarter, 1995 (pages 68 and 69).

Comment: One commenter, while approving the movement of codes 37.63, 37.65, and 37.66 to DRG 525, did not believe that cases with code 37.62 belong in this DRG. The commenter stated that code 37.62 includes centrifugal pumps, heart assist systems that are not specified as pulsatile, and the insertion of not otherwise specified heart assist systems, and urged CMS to reconsider inclusion of this code in the new DRG. The commenter stated that centrifugal pumps are more similar to cardiac bypass procedures than to ventricular assist systems, and inclusion of this code would likely reduce the relative weight of DRG 525 due to the lower cost of this type of technology. The commenter recommended that code 37.62 remain in DRG 104 and 105. The commenter was also concerned that the

change would create a potential incentive for these technologies to be used for purposes not yet approved by the FDA.

Response: Our analysis indicates that these four codes represent the most expensive cases in MDC 5, aside from heart transplantation in DRG 103, which is the reason we moved them out of DRGs 104 and 105. However, we will continue to evaluate the appropriate assignment of cases into this new DRG, particularly if new uses for heart assist systems are approved by the FDA, and will take the commenter's recommendation into account when we conduct our annual MedPAR review next year.

Comment: One commenter suggested that we develop a new heart transplant DRG entitled "Heart Transplant with LVAD," because the costs of the LVADs have not been incorporated into the heart transplant DRG. The commenter stated that, since a great number of LVAD cases remain inpatients until heart transplant occurs, there is a disparity in costs between heart transplant patients who receive LVADs during the stay, and those who do not remain inpatients.

Response: As we pointed out above, cases in which a subsequent heart transplant occurs during the hospitalization episodes are currently assigned to DRG 103 (Heart Transplant) because cases involving procedure codes 33.6 (Combined heart/lung transplant) and 37.5 (Heart transplant) are assigned to DRG 103, regardless of other codes included on the bill. We believe these cases are appropriately compensated in these DRGs, but we will continue to monitor this issue in the future.

Comment: One commenter requested that we review our data to determine if there is an incorrect mix of devices being included in the calculation of the DRG weight. The commenter suggested that perhaps that there is some inappropriate mixing of data, and that there are temporary assist devices used in the intensive care unit (ICU) that are quite distinct from those used for longer term bridge-to-transplant. This commenter noted that these ICU devices are much less expensive.

Response: As noted in the proposed rule, average length of stay and charge data were calculated for all cases including codes 37.62, 37.63, 37.65, and 37.66. These codes describe the implantation of heart assist systems, which is the construct of the new DRG 525. Therefore, we believe we have appropriately accounted for these cases in our analysis.

Comment: One commenter expressed concern that we did not separate payment for LVADs used in the acute care setting from LVADs used as chronic care devices, and pointed out that the short-term indication uses only a fraction of the resources required for a chronic or long-term LVAD. The commenter asked us to consider two DRGs, one for acute care devices and one for long-term care devices, that better reflect the resource consumption of each indication.

Response: The LVAD is currently being studied as a device that would support end-stage heart failure patients in the absence of a heart transplant. This use is not out of the clinical trial phase and, more importantly, has not been recognized as a Medicare covered service. It would be premature to establish a DRG based on the possibility that the LVAD may some day be approved for this indication is premature.

b. Moving Diagnosis Code 398.91 (Rheumatic Heart Failure) From DRG 125 to DRG 124

DRG 124 (Circulatory Disorders Except Acute Myocardial Infarction (AMI), with Cardiac Catheterization and Complex Diagnosis) and DRG 125 (Circulatory Disorders Except Acute Myocardial Infarction (AMI) with Cardiac Catheterization without Complex Diagnosis) have a somewhat complex DRG logic. In order to be assigned to DRG 124 or 125, the patient must first have a circulatory disorder, which would be one of the diagnoses included in MDC 5. However, these DRGs exclude acute myocardial infarctions. Therefore, these DRGs are comprised of cases with a diagnosis from MDC 5, excluding acute myocardial infarction, but also with a cardiac catheterization during the stay.

DRGs 124 and 125 are then further defined by whether or not the patient had a complex diagnosis. If the patient has a complex diagnosis, the case is assigned to DRG 124. If the patient does not have a complex diagnosis, the case is assigned to DRG 125. A list of diagnoses that comprise complex diagnoses is identified within DRG 124. These diagnoses can be listed as either a principal or secondary diagnosis.

We have received correspondence regarding the current assignment of diagnosis code 398.91 (Rheumatic heart failure). The correspondent pointed out that, while other forms of heart failure are listed as complex diagnoses under DRG 124, rheumatic heart failure is not included as a complex diagnosis within that DRG. Currently, if a patient with rheumatic heart failure receives a

cardiac catheterization, the case is assigned to DRG 125.

The correspondent had conducted a study and found that patients with rheumatic heart failure who receive a cardiac catheterization have lengths of stay that are significantly longer than patients with other forms of heart failure who receive a cardiac catheterization and who are assigned to DRG 125. The correspondent found that these patients have lengths of stay more similar to those cases assigned to DRG 124 (which have other forms of heart failure), and recommended that diagnosis code 398.91 be added to the list of complex diagnoses within DRG 124.

Within our claims data, we found 439 cases of patients in DRG 125 with rheumatic heart failure that received a cardiac catheterization. The average charges for these rheumatic heart failure cases were almost twice as much as for other cardiac patients in DRG 125 who received a cardiac catheterization and who did not have a diagnosis of rheumatic heart failure. We also conferred with our medical consultants and they agree that rheumatic heart failure with cardiac catheterization is a complex diagnosis and should be assigned to DRG 124 along with the other complex forms of heart failure cases involving cardiac catheterization.

We proposed to add code 398.91 to DRG 124 as a complex diagnosis. As a result, catheterization cases with rheumatic heart disease would no longer be assigned to DRG 125.

Several commenters representing hospitals and medical coders supported our proposal to classify code 398.91 as a complex diagnosis within DRG 124, which moves these cases from DRG 125. Accordingly, we are adopting as final the proposed change.

c. Radioactive Element Implant

In the August 1, 2001 final rule, we created DRG 517 (Percutaneous Cardiovascular Procedure without Acute Myocardial Infarction (AMI) with Coronary Artery Stent Implant) as a result of the overall DRG splits based on the presence of AMI (66 FR 39839). We assigned code 92.27 (Implantation or insertion of radioactive elements) to DRG 517 because we believed that code 92.27 would always accompany cases involving a percutaneous cardiovascular procedure and intravascular radiation treatment.

We have since determined that code 92.27 can also be present as a stand-alone code in other types of cases. When cases with an MDC principal diagnosis and code 92.27 do not meet the criteria for assignment to DRG 517 because there is no indication of a percutaneous

cardiovascular procedure, they are currently assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis). Because DRG 468 is reserved for cases in which the O.R. procedure is unrelated to the principal diagnosis, we proposed to assign cases with code 92.27 that do not meet the criteria for assignment to DRG 517, but that would otherwise be assigned to MDC 5, to DRG 120 (Other Circulatory System O.R. Procedures).

Comment: One commenter supported the proposal. Another commenter was unclear why code 92.27 is designated as an operating room procedure and would be assigned to DRG 120 (Other Circulatory System O.R. Procedures) if reported as a stand-alone procedure. This commenter stated that it is not aware of instances when it is appropriate to report this code without a concomitant cardiovascular procedure, and believed that another procedure, such as angioplasty, is needed in order to insert the radioactive implants. The commenter believed that cases in which code 92.27 was reported by itself for treatment of a cardiovascular disorder may represent incorrect coding.

Response: We proposed this modification to MDC 5 (Diseases and Disorders of the Circulatory System), concerning the assignment of code 92.27 (when reported as the only procedure) to DRG 120 in part, as a result of a telephone call from a member of the general public. The inquirer questioned the assignment of code 92.27 without angioplasty and with a principal diagnosis in MDC 5 to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis). When we created DRG 517 in the FY 2002 final rule, we also did not consider that a radioactive implant would be inserted without angioplasty as a delivery technique. We were advised by our medical advisors that it could occur, but it was unlikely. Code 92.27 has not yet been reported in our MedPAR data in MDC 5 as a stand-alone procedure. However, to address the possibility that it might be reported alone, we are taking this opportunity to assign code 92.27 to DRG 120 in MDC 5, consistent with the principal diagnosis, instead of a (higher-weighted) DRG in which the principal diagnosis and the procedure do not match (DRG 468).

With regard to the commenter's question about the designation of code 92.27 as an operating room procedure, we note that code 92.27 has always been considered by the Medicare GROUPER to be a procedure code affecting DRG assignment. It can be found in 12 MDCs and 20 DRGs in GROUPER version 19.0.

Comment: One commenter commended us for responding to its previously submitted comments concerning inadequate DRG payment for GP IIB–IIIA platelet inhibitors, but noted that its request from last year was not mentioned in our proposed rule in our review of several cardiovascular DRGs for both interventional and medical cases that receive GP IIB–IIIA inhibitors. The commenter stated that without a review of the presence of code 99.20 (Injection or infusion of platelet inhibitor) in DRGs 124 (Circulatory Disorders Except AMI, with Cardiac Catheterization and Complex Diagnosis) and 140 (Angina Pectoris), CMS cannot be certain that a significant number of cases are not significantly underpaid.

Response: We regret this omission in the proposed rule. We did, in fact review both DRGs 124 and 140 for the presence of code 99.20. In DRG 124, there were a total of 95,452 cases without code 99.20. These cases had an average length of stay of 4.4 days and average charges of \$17,594. There were 1,120 cases in DRG 124 with code 99.20.

These cases had an average length of stay of 3.5 days, and average charges of \$17,256. In DRG 140, there were a total of 45,886 cases without code 99.20, with an average length of stay of 2.5 days and average charges of \$6,204. There were 126 cases in DRG 140 with code 99.20, with an average length of stay of 2.3 days, and average charges of \$8,675.

The data do not demonstrate a level of disparity in days and charges that would warrant an adjustment to these DRGs based on the presence of code 99.20. Therefore, we are not making any changes concerning the status of code 99.20 in these DRGs for FY 2003.

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)

Currently, when ICD–9–CM code 277.00 (Cystic Fibrosis without mention of meconium ileus) is reported as the principal diagnosis, it is assigned to the following DRG series in MDC 10: DRG 296 (Nutritional and Metabolic Disease, Age >17 with CC); DRG 297 (Nutritional and Metabolic Disease, Age >17 without CC); and DRG 298 (Nutritional and Metabolic Disease, Age 0–17).

As part of our annual review of DRG assignments and based on correspondence that we have received, we examined cases involving code 277.00 as a principal diagnosis in DRGs 296, 297, and 298. Our analysis of the average charges for these cases indicates that resource utilization for these cases is quite different from resource utilization for other cases in these three DRGs. We believe that this difference in resource utilization is due to the fact it

is not uncommon for cystic fibrosis patients to be admitted with pulmonary complications. Our findings on the number of cases and the average charges in the three DRGs when code 277.00 is assigned as the principal diagnosis, and our findings for all cases in the three DRGs, are indicated in the charts below.

CASES IN DRG, 296, 297, AND 298 WITH CODE 277.00 AS THE PRINCIPAL DIAGNOSIS

DRG and description	Number of cases	Average charges
DRG 296 (Nutritional & Metabolic Disease Age >17 with CC)	271	\$34,111
DRG 297 (Nutritional & Metabolic Disease Age >17 without CC)	133	21,998
DRG 298 (Nutritional & Metabolic Disease Age 0-17)	0

ALL CASES IN DRG 296, 297, 298

DRG 298 description	Number of cases	Average charges
DRG 296 (Nutritional & Metabolic Disease Age >17 with CC)	169,768	\$10,480
DRG 297 (Nutritional & Metabolic Disease Age >17 without CC)	31,560	6,190
DRG 298 (Nutritional & Metabolic Disease Age 0-;17) ...	17	8,603

Based on the results of our analysis, we proposed that three new cystic fibrosis principal diagnosis codes be assigned to specific DRGs and MDCs, and that other changes be made to DRG and MDC assignments of existing cystic fibrosis codes, as discussed below.

We proposed to use the following three new principal diagnosis codes to further inform DRG assignment of these patients:

- 277.02 (Cystic fibrosis with pulmonary manifestations)
- 277.03 (Cystic fibrosis with gastrointestinal manifestations)
- 277.09 (Cystic fibrosis with other manifestations)

We proposed that existing code 277.01 (Cystic fibrosis with mention of meconium ileus) would continue to be assigned to DRG 387 (Prematurity with Major Problems) and DRG 389 (Full Term Neonate with Major Problems) in MDC 15 (Newborns and Other Neonates with Conditions Originating in the

Perinatal Period), since it is a newborn diagnosis code.

Because the new code 277.02 would identify those patients with cystic fibrosis who have pulmonary manifestations, we proposed to assign cases in which this is the principal diagnosis to DRG 79 (Respiratory Infection and Inflammations Age >17 with CC), DRG 80 (Respiratory Infections and Inflammations Age >17 without CC), or DRG 81 (Respiratory Infections and Inflammations Age 0-17) in MDC 4 (Diseases and Disorders of the Respiratory System).

We proposed that the new code 277.03 would be assigned to DRG 188 (Other Digestive System Diagnoses Age >17 with CC), DRG 189 (Other Digestive System Diagnoses Age >17 without CC), and DRG 190 (Other Digestive System Diagnoses Age 0-17) in MDC 6 (Diseases and Disorders of the Digestive System), because of its specific relationship to the digestive system.

Since the new code 277.09 could involve a number of manifestations (excluding pulmonary and gastrointestinal), we proposed to assign this new code to DRGs 296, 297, and 298 in MDC 10, where we are retaining the current assignment of existing code 277.00.

The following chart summarizes our proposed DRG and MDC assignments for new and existing cystic fibrosis principal diagnosis codes:

Principal diagnosis code and description	MDC assignment	DRG assignments
Existing 277.00 (Cystic fibrosis without mention of meconium ileus)	10	296, 297, 298
Existing 277.01 (Cystic fibrosis with mention of meconium ileus)	15	387, 389
New 277.02 (Cystic fibrosis with pulmonary manifestations)	4	79, 80, 81
New 277.03 (Cystic fibrosis with gastrointestinal manifestations)	6	188, 189, 190
New 277.09 (Cystic fibrosis with other manifestations)	10	296, 297, 298

Several commenters representing hospitals, medical coders, and specialty groups supported the proposed DRG assignments relating to cystic fibrosis discussed above. Therefore, we are adopting the proposed DRG assignments as final, effective for discharges occurring on or after October 1, 2002.

5. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)

a. Insertion of Totally Implantable Vascular Access Device (VAD)

In the August 1, 2001 final rule (66 FR 39844), we discussed our review of the DRG assignment of code 86.07 (Insertion of totally implantable vascular access device (VAD)). Code 86.07 is considered a nonoperative procedure when it occurs in MDC 11. In other words, the Medicare GROUPER software program does not recognize code 86.07 as a procedure code when reported with any principal diagnosis in this MDC. Therefore, patients in renal (kidney) failure requiring implantation of this device for dialysis are grouped to medical DRG 316 (Renal Failure). We examined whether implantation of this device should be removed from DRG 316 and placed into surgical DRG 315 (Other Kidney and Urinary Tract O.R. Procedures).

Implantation of a VAD into the chest wall and blood vessels of a patient's upper body allows access to a patient's vessels via an implanted valve and cannula. Two devices are implanted during one operative session. One system is implanted arterially (the "draw"), while the other is implanted venous (the "return"). Typically, the VAD allows access to the patient's blood for hemodialysis purposes when other sites in the body have been exhausted. The device is usually inserted in the outpatient setting. Operative time is approximately 1 to 1.5 hours.

In the FY 2002 final rule (66 FR 39844-39845), we pointed out that cases where the VAD was inserted as an inpatient procedure often involved complications, leading to higher average charges and longer lengths of stay for those cases. Therefore, we indicated that we would not assign code 86.07 to DRG 315 at that time, but we would consider other alternative adjustments to DRGs 315 and 316.

For FY 2003, we explored whether DRG 315 should be divided based on the presence or absence of CCs. However, during our consideration of this alternative, we discovered that DRG 315 does not lend itself to a CC split due to the high occurrence of cases in this DRG that already have complications identified on the CC list. Therefore, we

reexamined cases in DRGs 315 and 316 in the FY 2001 MedPAR file. The results are reflected in the chart below:

	With code 86.07	Without code 86.07
DRG 315 (Surgical):		
Number of Cases	354	21,089
Average Length of Stay	12.6 days	6.7 days
Average Charges	\$47,251	\$25,622
DRG 316 (Medical):		
Number of Cases	887	76,676
Average Length of Stay	10.3	6.6 days
Average Charges	\$31,904	\$16,934

These results are similar to the findings included in the FY 2002 final rule that were based on data from the FY 2000 MedPAR file (66 FR 39845).

We found that the average length of stay in DRG 315 for patients not receiving the VAD is 6.7 days, while those patients who received the VAD had an average length of stay of 12.6 days. We found the average charges in DRG 315 for patients not receiving the VAD were approximately \$25,622, while the average charges for those patients who received the VAD were \$47,251.

We found that the cases receiving the VAD as an inpatient procedure are significantly more costly than other cases in DRG 316. Therefore, we proposed to designate code 86.07 as an O.R. procedure under MDC 11.

Specifically, code 86.07 will be recognized as an O.R. procedure code in MDC 11 and assigned to DRG 315 when combined with the following principal diagnosis codes from DRG 316:

- 403.01, Malignant hypertensive renal disease with renal failure
- 403.11, Benign hypertensive renal disease with renal failure
- 403.91, Unspecified hypertensive renal disease with renal failure
- 404.02, Malignant hypertensive heart and renal disease with renal failure
- 404.12, Malignant hypertensive heart and renal disease with renal failure
- 404.92, Unspecified hypertensive heart and renal disease with renal failure
- 584.5, Acute renal failure with lesion of tubular necrosis
- 584.6, Acute renal failure with lesion of renal cortical necrosis
- 584.7, Acute renal failure with lesion of renal medullary (papillary) necrosis
- 584.8, Acute renal failure with other specified pathological lesion in kidney

- 584.9, Acute renal failure, unspecified
- 585, Chronic renal failure
- 586, Renal failure, unspecified
- 788.5, Oliguria and anuria
- 958.5, Traumatic anuria

We received two comments in support of this proposal. Therefore, we are adopting as final the proposed redesignation of code 87.06 as an O.R. procedure under MDC 11 and its assignment to DRG 315 when combined with the principal diagnosis codes from DRG 316 listed above.

b. Bladder Reconstruction
We received correspondence regarding the current classification of procedure code 57.87 (Reconstruction of urinary bladder) as a minor bladder procedure and the assignment of the code under DRG 308 (Minor Bladder Procedures with CC) and DRG 309 (Minor Bladder Procedures without CC). The correspondent believed that bladder reconstruction is not a minor procedure, submitted individual hospital charges to support this contention, and recommended that the code be classified as a major procedure and assigned to a higher weighted DRG.

Our clinical advisors indicated that reconstruction of the bladder is a more extensive procedure than the other minor bladder procedures in DRGs 308 and 309. They agree that the bladder reconstruction procedure is as complex as the procedures under code 57.79 (Total cystectomy) and the other major bladder procedures in DRGs 303 through 305.

As indicated in the chart below, we found that the average charges for bladder reconstruction are significantly higher than the average charges for other minor procedures within DRGs 308 and 309:

	With code 57.87	Without code 57.87
DRG 308 (Minor Bladder Procedure with CC):		
Number of Cases ..	64	5,066
Average Charges ..	\$36,560	\$19,923
DRG 309 (Minor Bladder Procedures without CC):		
Number of Cases ..	25	3,021
Average Charges ..	\$23,390	\$11,200

We found that procedure code 57.87 may be more appropriately placed in DRG 303 (Kidney, Ureter and Major Bladder Procedures for Neoplasm), 304 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm with CC), and DRG 305 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm

without CC), based on average charges for procedures in these three DRGs as indicated in the following chart:

DRG	Number of cases	Average charges
303 (Kidney, Ureter and Major Bladder Procedures for Neoplasm)	14,116	\$30,691
304 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm with CC)	8,060	30,577
305 (Kidney, Ureter and Major Bladder Procedures for Nonneoplasm without CC)	2,029	15,492

Based on the results of our analysis and the advice of our medical consultants discussed above, we proposed to classify code 57.87 as a major bladder procedure and to assign it to DRGs 303, 304, and 305.

We received several comments from associations representing hospitals and medical coders in support of the proposed reclassification of bladder reconstruction surgery from a minor bladder to a major bladder procedure. Accordingly, we are adopting as final the proposed reclassification, effective for discharges occurring on or after October 1, 2002.

6. MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period)

The primary focus of updates to the Medicare DRG classification system is for changes relating to the Medicare patient population, not the pediatric or neonatal patient populations. However, the Medicare DRGs are sometimes used to classify other patient populations. Over the years, we have received comments about aspects of the Medicare newborn DRGs that appear problematic, and we have responded to these on an individual basis. Some correspondents have requested that we take a closer overall look at the DRGs within MDC 15.

Because of our limited data and experience with newborn cases under Medicare, we contacted the National Association of Children's Hospitals and Related Institutions (NACHRI), along with our own medical advisors, to obtain proposals for possible revisions of the existing DRG categories in MDC 15. The focus of the requested proposals was to refine category definitions within the framework of the existing seven broadly defined neonatal DRGs. The proposals also were to take advantage of the new, more specific neonatal

diagnosis codes to be adopted, effective October 1, 2002, to assist with refinements to the existing DRG category definitions.

In the May 9, 2002 proposed rule, we proposed to make extensive changes to multiple DRG categories in MDC 15. A complete description of these proposed changes appears in the May 9, 2002 **Federal Register** at 67 FR 31412 through 31414. In summary, the proposed changes involved removing a number of congenital anomalies from MDC 15 and assigning them to other MDCs. NACHRI advised us that these congenital anomalies would be better classified in the MDC for the body system affected. We also proposed revising DRG 386 (Extreme Immaturity or Respiratory Distress Syndrome, Neonate), to refine the assignment of newborn cases diagnosed with extreme immaturity. We proposed major revisions for DRG 387 (Prematurity With Major Problems) to redefine the codes for prematurity and the codes that define a "major problem". We proposed modifications of DRG 388 (Prematurity Without Problems), which involved changes in the classification of prematurity for newborns. We proposed revising the definition of a "major problem" for DRG 389 (Full Term Neonate With Major Problem) as well. By changing the definition of "major problem" in the other DRGs, our proposal would have increased the number of cases being assigned to DRG 390. Finally, we proposed to expand the number of minor problem newborn diagnoses included in DRG 391 (Normal Newborn). All of these extensive changes would have greatly shifted the DRG assignments for newborns, involving hundreds of ICD-9-CM codes.

Comment: One commenter, a national hospital association, opposed at this time the reassignment of a large number of diagnosis codes from the "major problems" list in DRGs 387 and 389 to DRG 391. The commenter agreed that refinements to MDC 15 would be beneficial to allow more accurate grouping of neonatal admissions but recommended that, prior to making extensive changes, CMS work with NACHRI, the commenter, and other interested parties to develop a separate DRG that would group neonates with minor problems that are not otherwise recognized currently or under the proposed changes.

Other commenters, representing hospitals, medical groups, and medical coders, offered a similar comment. One commenter stated that since NACHRI represents specialty hospitals, NACHRI's data may not fully represent the entire newborn population. Other

commenters recommended that the proposed revisions to DRGs 387 through 391 not be implemented until input is obtained from representatives of general community hospitals that treat newborns. The commenters stated that newborn DRG data from general community hospitals may vary significantly from NACHRI's data and should be taken into consideration prior to implementing the proposed revisions to DRGs 387 through 391.

One commenter also stated that, while it supported the proposed removal of the listed codes for congenital anomalies, periventricular leukomalacia, and nonspecific abnormal findings on chromosomal analysis from MDC 15, the commenter was confused as to the rationale for the proposed DRG assignments for the codes for congenital anomalies. (We proposed that code 759.4, Conjoined twins, be classified to DRGs 188, 189, and 190.) In addition, several commenters stated that these DRGs are for digestive system diagnoses and conjoined twins may or may not have medical conditions involving the digestive system. The commenters stated that the rationale for the selection of these DRGs was not described in the proposed rule.

One commenter stated that additional study of newborn DRG classifications was needed. This commenter recommended that when cardiac surgery procedures are performed on neonates born in the hospital, the case be assigned to the applicable cardiac surgery DRG instead of one of the neonatal DRGs. The commenter pointed out that when a baby is born in a hospital and surgery is performed on a congenital heart condition during the same stay, the newborn is assigned to DRG 389 where the relative weight is approximately one-half the weight of the applicable cardiac surgery DRG. When the newborn is delivered at another facility and then transferred for surgery, the newborn is assigned to the appropriate cardiac surgery DRG. The commenter recommended that this issue be considered when MDC 15 is revised.

Response: The commenters raised a number of important issues. We solicited the assistance of NACHRI to develop refinements to MDC 15 because, while MDC 15 is part of the Medicare DRG system, the types of patients in classified to DRGs in MDC 15 are not a significant part of the Medicare program. It was our goal to develop refinements that could be useful for non-Medicare purposes. Given the extensive nature of the proposed revisions, we concur that additional study is necessary. Therefore, we are not implementing as final any of

the proposed revisions to MDC 15. We are maintaining the existing structure of DRGs 385 through 390 within MDC 15 (Version 19.0) for FY 2003. Nonetheless we believe that changes in this area may be worthwhile, and we would be interested in considering a set of appropriate changes that might be broadly acceptable to the affected community. If we receive such suggested changes by December 1, 2002, we would consider it as part of our annual review and updates to the DRG system for FY 2004. Any proposals could be included in the notice of proposed rulemaking for FY 2004, which is scheduled to be published in early Spring 2003. In the meantime, as stated earlier, we are not making any of the proposed changes to MDC 15 for FY 2003.

Comment: One commenter supported the creation of the new ICD-9-CM codes that differentiate between extreme immaturity or gestational age, or both.

Response: As explained in the proposed rule, we are adding the new ICD-9-CM codes for newborns that were approved in 2002 for use by acute care hospitals in FY 2003. These codes are listed in Table 6A of this final rule. The codes are assigned to the existing DRGs as indicated in Table 6A under the column "DRG" (codes 747.83 through 779.89). Tables 6A through 6F in this final rule also reflect the assignment of these new codes.

Comment: One commenter pointed out several typographical errors and omissions in the proposed changes for MDC 15 in the proposed rule.

Response: The commenter is correct that there were typographical errors in the proposed rule. However, since we are not finalizing the proposed changes, we are not addressing the errors specifically in this final rule. We will provide clarifications of these errors to those interested parties who participating in future efforts to refine MDC 15.

7. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services)

In the August 1, 2001 final rule, we included in Table 6A-New Diagnosis Codes (66 FR 40064) code V10.53 (History of malignancy, renal pelvis), which was approved by the ICD-9-CM Coordination and Maintenance Committee as a new code effective October 1, 2001. We assigned the code to DRG 411 (History of Malignancy without Endoscopy) and DRG 412 (History of Malignancy with Endoscopy).

We received correspondence that suggested that we should have also

assigned code V10.53 to DRG 465 (Aftercare with History of Malignancy as Secondary Diagnosis). The correspondent pointed out that all other codes for a history of malignancy are included in DRG 465.

We agree that code V10.53 should be included in the list of the history of malignancy codes within DRG 465.

We received several comments in support of this change. Accordingly, in this final rule we are adding code V10.53 to the list of secondary diagnosis in DRG 465, effective for discharges occurring on or after October 1, 2002.

8. Pre-MDC: Tracheostomy

DRG 483 (Tracheostomy Except for Face, Mouth and Neck Diagnoses) is used to classify patients who require long-term mechanical ventilation. Mechanical ventilation can be administered through an endotracheal tube for a limited period of time. When an endotracheal tube is used for an extended period of time (beyond 7 to 10 days), the patient runs a high risk of permanent damage to the trachea. In order to maintain a patient on mechanical ventilation for a longer period of time, the endotracheal tube is removed and a tracheostomy is performed. The mechanical ventilation is then administered through the tracheostomy.

A tracheostomy also may be performed on patients for therapeutic purposes unrelated to the administration of mechanical ventilation. Patients with certain face, mouth, and neck disease may have a tracheostomy performed as part of the treatment for the face, mouth, or neck disease. These patients are assigned to DRG 482 (Tracheostomy for Face, Mouth and Neck Diagnoses).

Therefore, patients assigned to DRGs 482 and 483 are differentiated based on the principal diagnosis of the patient. At certain times, selecting the appropriate principal diagnosis for the patients receiving tracheostomies for assignment to a DRG can be difficult. The overall number of tracheostomy patients increased by 13 percent between 1994 and 1999. During the same period, the percent of tracheostomy patients in DRG 483 (patients without certain face, mouth, or neck diseases) versus DRG 482 increased from 83.6 percent to 87.6 percent.

The payment weight for DRG 483 is more than four times greater than the DRG 482 payment weight, and this has led to concerns about coding compliance. Specifically, the fact that cases are assigned to DRG 483 based on the absence of a code indicating face, mouth, or neck diagnosis creates an

incentive to omit codes indicating these diagnoses.

To address issues of possible coding noncompliance, we proposed to modify DRGs 482 and 483 to differentiate the assignment to either DRG based on the presence or absence of continuous mechanical ventilation that lasts more than 96 hours (code 96.72). This modification would ensure that the patients assigned to DRG 483 are patients who had the tracheostomy for long-term mechanical ventilation. Based on an examination of claims data from the FY 2001 MedPAR file, we found that many patients assigned to DRG 483 do not have the code 96.72 for continuous mechanical ventilation for 96 consecutive hours or more recorded. In part, this is the result of the limited number of procedure codes (six) that can be submitted on the current uniform hospital claim form, and the fact that code 96.72 does not currently affect the DRG assignment.

We proposed to change the definition of DRG 483 so that patients who have a tracheostomy and continuous mechanical ventilation greater than 96 hours (code 96.72) would be assigned to DRG 483. We would continue to assign to DRG 483 those patients who have a principal diagnosis unrelated to disease of the face, mouth, or neck and a tracheostomy. We proposed to retitle DRG 483 "Tracheostomy/Mechanical Ventilation 96+ Hours Except Face, Mouth, and Neck Diagnosis."

In the proposed rule, we indicated that we would give future consideration to modifying DRGs 482 and DRG 483 based on the presence of code 96.72, and specifically invited comments on this area.

Comment: Several commenters representing hospital associations and medical groups supported the proposed modification to DRG 483. Some commenters strongly supported using code 96.72 as a determining factor for assigning ventilator patients to DRG 483. Another commenter indicated that the proposal was a more accurate means of identifying high-cost ventilator patients.

One commenter representing medical coders opposed the proposed modification. The commenter expressed concern that there were no supporting data to justify the revision. The commenter pointed out that it was not clear to which DRG tracheostomy patients with mechanical ventilation of less than 96 hours and with out a face, neck, or mouth diagnosis would be classified, since no modification to DRG 482 was proposed. The commenter did note that CMS was encouraging the reporting of code 96.72, but believed

that this might be a problem when a number of other significant operative procedures are performed, given the limited spaces available on the claim form to report ICD-9-CM procedure codes.

Response: The proposed change was a first attempt to refine DRGs 482 and 483 so that those patients who receive long-term (> 96 hours) mechanical ventilation are separated from those patients who receive mechanical ventilation of less than 96 hours. The proposed change to DRG 483 was partially in response to concern that hospitals could omit diagnosis codes indicating face, mouth, or neck diagnosis in order to have cases assigned to DRG 483 rather than the much lower paying DRG 482. It also was an attempt to improve the classification of patients on mechanical ventilation by identifying those who receive long-term use of a ventilator. By making the GROUPER recognize long-term mechanical ventilation and assigning those patients to the higher weighted DRG 483, we hoped that hospitals would be more aware of the importance of reporting code 96.72 when, in fact, patients had been on the ventilator for greater than 96 hours. Therefore, hospitals would appropriately increase the reporting of this code. This reporting would allow us to continue to refine DRGs 482 and 483 to better reflect the resource utilization of these cases.

We agree with the commenter that hospitals frequently are faced with cases where more than six procedures are performed during the inpatient stay and that there are limited spaces available on the claims form for reporting procedure codes. The proposed change encourages hospitals to begin to report code 96.72, since it will effect DRG assignment.

The commenter was correct; we were not completely clear in the proposed rule about the effect that the addition of code 96.72 would have on DRG 482. The change will have an impact on DRG 482. All cases involving a tracheostomy and a diagnosis of face, mouth, and neck diagnosis that also have been on continuous mechanical ventilation for greater than 96 hours (code 96.72) will be moved out of DRG 482 and into DRG 483. The effect is that the expensive, long-term mechanical ventilation cases will be moved out of DRG 482 and into the higher-weighted DRG 483. As mentioned earlier, we did not propose any DRG modification involving patients who receive a tracheostomy, have mechanical ventilation of less than 96 hours, and do not have a face, neck, or mouth diagnosis. These cases will continue to be assigned to DRG 483.

Should future data indicate a need for further refinement of DRGs 482 and 483, we would propose these changes at that time. The public would be given an opportunity to comment on these proposals through the normal notice-and-comment rulemaking process.

In this final rule, we are adopting as final the proposed change in the definition of DRG 483 and the proposed change to add code 96.72 to DRG 483. To further clarify this change, we are changing the title of DRG 483 to "Tracheostomy with Mechanical Ventilation 96 + Hours or Principal Diagnosis Except Face, Mouth, and Neck."

9. Medicare Code Editor (MCE) Change

As explained under section II.B.1. of this preamble, the MCE is a software program that detects and reports errors in the coding of Medicare claims data.

The MCE includes an edit for "nonspecific principal diagnosis" that identifies a group of codes that are valid according to the ICD-9-CM coding scheme, but are not as specific as the coding scheme permits. The fiscal intermediaries use cases identified in this edit for educational purposes for hospitals only. That is, when a hospital reaches a specific threshold of cases (usually 25) in this edit, the fiscal intermediary will contact the hospital and educate it on how to code diagnoses using more specific codes in the ICD-9-CM coding scheme.

Code 436 (Acute, but ill-defined, cerebrovascular disease) is one of the codes included in the groups of codes identified in the nonspecific principal diagnosis edit, and is widely used in smaller hospitals where testing mechanisms are not available or have not been utilized to more specifically identify the location and condition of cerebral and precerebral vessels. Because of the frequent use of code 436 among smaller hospitals, we proposed to remove the code from the nonspecific principal diagnosis edit in the MCE. We address the use of code 436 in section II.B.3. of this final rule under the discussion of MDC 5 changes with regard to the remodeling of DRGs 14 and 15.

We received two comments in support of this proposal. However, one of the commenters noted that code 436 is not just limited to use in smaller hospitals, as we stated in the proposed rule. We acknowledge the commenters' remarks that code 436 is widely used in hospitals of all sizes and is not exclusively used in smaller hospitals. However, our rationale for removing code 436 from the MCE because it is frequently used, still holds.

Accordingly, we are adopting as final the proposed removal of code 436 from the MCE "nonspecific principal diagnosis" edit, effective with discharges occurring on or after October 1, 2002.

10. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Its application ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of DRG reclassification and recalibrations, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more DRGs. For example, in MDC 11, the surgical class "kidney transplant" consists of a single DRG (DRG 302) and the class "kidney, ureter and major bladder procedures" consists of three DRGs (DRGs 303, 304, and 305). Consequently, in many cases, the surgical hierarchy has an impact on more than one DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes DRGs 1 and 2 and surgical class B includes DRGs 3, 4, and 5. Assume also that the average charge of DRG 1 is higher than that of DRG 3, but the average charges of DRGs 4 and 5 are higher than the average charge of DRG 2. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weight the average charge of each DRG in the class by frequency (that is, by the number of cases in the DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of "other O.R. procedures" as discussed below.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER searches for the procedure in the most resource-intensive surgical class, this result is unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average charge is ordered above a surgical class with a higher average charge. For example, the "other O.R. procedures" surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average charge for the DRG or DRGs in that surgical class may be higher than that for other surgical classes in the MDC. The "other O.R. procedures" class is a group of procedures that are only infrequently related to the diagnoses in the MDC but are still occasionally performed on patients in the MDC with these diagnoses. Therefore, these procedures should only be considered if no other procedure more closely related to the diagnoses in the MDC has been performed.

A second example occurs when the difference between the average charges for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy since, as a result of the hierarchy change, the average charges are likely to shift such that the higher-ordered surgical class has a lower average charge than the class ordered below it.

In the May 9, 2002, we proposed to revise the surgical hierarchy for the pre-MDC DRGs and for MDC 5 (Diseases and Disorders of the Circulatory System) as follows:

- In the pre-MDC DRGs, we proposed to reorder DRG 495 (Lung Transplant) above DRG 512 (Simultaneous Pancreas/Kidney Transplant).
- In MDC 5, we proposed to reorder DRG 525 (Heart Assist System Implant) above DRGs 104 and 105 (Cardiac Valve and Other Major Cardiothoracic Procedures with and without Cardiac Catheterization, respectively).

In the proposed rule, we were unable to test the effects of the proposed revisions to the surgical hierarchy and to reflect these changes in the proposed relative weights because the revised GROUPER software was unavailable at the time the proposed rule was completed. Rather, we simulated most major classification changes to

approximate the placement of cases under the proposed reclassification, and then determined the average charge for each DRG. These average charges served as our best estimate of relative resources used for each surgical class. We have now tested the proposed surgical hierarchy changes after the revised GROUPER was received and are reflecting the final changes in the DRG relative weights in this final rule. Further, as discussed in section II.C. of this preamble, the final recalibrated weights are somewhat different from the proposed weights because they were based on more complete data.

Based on a test of the proposed revisions using the April 2002 update of the FY 2001 MedPAR file and the revised GROUPER software, we have found that the revisions are still supported by the data, and no additional changes are indicated except those discussed below pertaining to the implementation of two new cardiac drug-eluting stent DRGs. (For a complete description of this change, see the discussion under "Other Issues" in section II.B.14. of this preamble.) Due to the implementation of two new DRGs pertaining to cardiac drug-eluting stents, DRGs 526 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with AMI) and 527 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without AMI), we also are reordering the following DRGs in MDC 5: DRGs 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure or Stroke, or AICD Lead or and Generator Procedure) and 116 (Other Permanent Cardiac Pacemaker Implant) above DRG 526; DRG 526 above DRG 516 (Percutaneous Cardiovascular Procedures with Acute Myocardial Infarction (AMI)); DRG 516 above DRG 527; DRG 527 above DRG 517 (Percutaneous Cardiovascular Procedure without AMI, with Coronary Artery Stent Implant); DRG 517 above DRG 518 (Percutaneous Cardiovascular Procedures without AMI, without Coronary Artery Stent Implant); and DRG 518 above DRGs 478 (Other Vascular Procedures with CC) and 479 (Other Vascular Procedures without CC).

11. Refinement of Complications and Comorbidities (CC) List

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. Thus, we created the CC Exclusions List. We made these

changes for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative coding or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. We developed this standard list of diagnoses using physician panels to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the standard list of CCs, either by adding new CCs or deleting CCs already on the list. In the May 9, 2002 proposed rule, we did not propose to delete any of the diagnosis codes on the CC list.

In the May 19, 1987 proposed notice (52 FR 18877) concerning changes to the DRG classification system, we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another (as subsequently corrected in the September 1, 1987 final notice (52 FR 33154)).
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. The FY 1988 revisions were intended only as a first step toward refinement of the CC list in that the criteria used for eliminating certain diagnoses from consideration as CCs were intended to identify only the most obvious diagnoses that should not be considered CCs of another diagnosis. For that reason, and in light of comments and questions on the CC list, we have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. (See the September 30, 1988 final rule (53 FR 38485) for the revision made for the discharges occurring in FY 1989; the September 1, 1989 final rule (54 FR

36552) for the FY 1990 revision; the September 4, 1990 final rule (55 FR 36126) for the FY 1991 revision; the August 30, 1991 final rule (56 FR 43209) for the FY 1992 revision; the September 1, 1992 final rule (57 FR 39753) for the FY 1993 revision; the September 1, 1993 final rule (58 FR 46278) for the FY 1994 revisions; the September 1, 1994 final rule (59 FR 45334) for the FY 1995 revisions; the September 1, 1995 final rule (60 FR 45782) for the FY 1996 revisions; the August 30, 1996 final rule (61 FR 46171) for the FY 1997 revisions; the August 29, 1997 final rule (62 FR 45966) for the FY 1998 revisions; the July 31, 1998 final rule (63 FR 40954) for the FY 1999 revisions, the August 1, 2000 final rule (65 FR 47064) for the FY 2001 revisions; and the August 1, 2001 final rule (66 FR 39851) for the FY 2002 revisions. In the July 30, 1999 final rule (64 FR 41490), we did not modify the CC Exclusions List for FY 2000 because we did not make any changes to the ICD-9-CM codes for FY 2000.

In this final rule, we are making limited revisions of the CC Exclusions List to take into account the changes that will be made in the ICD-9-CM diagnosis coding system effective October 1, 2002. (See section II.B.13. of this preamble for a discussion of ICD-9-CM changes.) These changes are being made in accordance with the principles established when we created the CC Exclusions List in 1987.

Tables 6G and 6H in the Addendum to this final rule contain the revisions to the CC Exclusions List that will be effective for discharges occurring on or after October 1, 2002. Each table shows the principal diagnoses with changes to the excluded CCs. Each of these principal diagnoses is shown with an asterisk, and the additions or deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis.

CCs that are added to the list are in Table 6G—Additions to the CC Exclusions List. Beginning with discharges on or after October 1, 2002, the indented diagnoses will not be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

CCs that are deleted from the list are in Table 6H—Deletions from the CC Exclusions List. Beginning with discharges on or after October 1, 2002, the indented diagnoses will be recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

Copies of the original CC Exclusions List applicable to FY 1988 can be obtained from the National Technical

Information Service (NTIS) of the Department of Commerce. It is available in hard copy for \$133.00 plus shipping and handling. A request for the FY 1988 CC Exclusions List (which should include the identification accession number (PB) 88-133970) should be made to the following address: National Technical Information Service, United States Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161; or by calling (800) 553-6847.

Users should be aware of the fact that all revisions to the CC Exclusions List (FYs 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, and 2002) and those in Tables 6F and 6G of this FY 2003 final rule must be incorporated into the list purchased from NTIS in order to obtain the CC Exclusions List applicable for discharges occurring on or after October 1, 2002. (Note: There was no CC Exclusions List in FY 2001 because we did not make changes to the ICD-9-CM codes for FY 2001.)

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current DRG Definitions Manual, Version 19.0, is available for \$225.00, which includes \$15.00 for shipping and handling. Version 20.0 of this manual, which includes the final FY 2002 DRG changes, is available for \$225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949-0303. Please specify the revision or revisions requested.

We received no comments on our proposed changes to the CC list, and we are adopting the changes as final.

12. Review of Procedure Codes in DRGs 468, 476, and 477

Each year, we review cases assigned to DRG 468 (Extensive O.R. Procedure

Unrelated to Principal Diagnosis), DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these DRGs.

DRGs 468, 476, and 477 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. DRG 476 is assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0 Incision of prostate
- 60.12 Open biopsy of prostate
- 60.15 Biopsy of periprostatic tissue
- 60.18 Other diagnostic procedures on prostate and periprostatic tissue
- 60.21 Transurethral prostatectomy
- 60.29 Other transurethral prostatectomy
- 60.61 Local excision of lesion of prostate
- 60.69 Prostatectomy NEC
- 60.81 Incision of periprostatic tissue
- 60.82 Excision of periprostatic tissue
- 60.93 Repair of prostate
- 60.94 Control of (postoperative) hemorrhage of prostate
- 60.95 Transurethral balloon dilation of the prostatic urethra
- 60.99 Other operations on prostate

All remaining O.R. procedures are assigned to DRGs 468 and 477, with DRG 477 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis. The original list of the ICD-9-CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV of the Addendum to the September 30, 1988 final rule (53 FR 38591). As part of the final rules

published on September 4, 1990 (55 FR 36135), August 30, 1991 (56 FR 43212), September 1, 1992 (57 FR 23625), September 1, 1993 (58 FR 46279), September 1, 1994 (59 FR 45336), September 1, 1995 (60 FR 45783), August 30, 1996 (61 FR 46173), and August 29, 1997 (62 FR 45981), we moved several other procedures from DRG 468 to 477, and some procedures from DRG 477 to 468. No procedures were moved in FY 1999, as noted in the July 31, 1998 final rule (63 FR 40962); in FY 2000, as noted in the July 30, 1999 final rule (64 FR 41496); in FY 2001, as noted in the August 1, 2000 final rule (65 FR 47064); or in FY 2002, as noted in the August 1, 2001 final rule (66 FR 39852).

a. Moving Procedure Codes From DRGs 468 or 477 to MDCs

We annually conduct a review of procedures producing assignment to DRG 468 or DRG 477 on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these DRGs into one of the surgical DRGs for the MDC into which the principal diagnosis falls. The data are arrayed two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical DRGs for the MDC in which the diagnosis falls. Based on this year's review, we did not identify any necessary changes in procedures under DRG 477. Therefore, we did not propose to move any procedures from DRG 477 to one of the surgical DRGs. However, we have identified a number of procedure codes that should be removed from DRG 468 and put into more clinically coherent DRGs. The assignments of these codes are specified in the charts below.

MOVEMENT OF PROCEDURE CODES FROM DRG 468

Procedure code	Description	Included in DRG	Description
MDC 6.—Diseases and Disorders of the Digestive System			
387	Interruption vena cava	170	Other Digestive System O.R. Procedures with CC.
387	Interruption vena cava	171	Other Digestive System O.R. Procedures without CC.
3950	Angioplasty or atherectomy of noncoronary vessel	170	Other Digestive System O.R. Procedures with CC.
3950	Angioplasty or atherectomy of noncoronary vessel	171	Other Digestive System O.R. Procedures without CC.

MDC 7—Diseases and Disorders of the Hepatobiliary System and Pancreas

387	Interruption vena cava	201	Other Hepatobiliary & Pancreas Procedures.
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MOVEMENT OF PROCEDURE CODES FROM DRG 468—Continued

Procedure code	Description	Included in DRG	Description
3949	Other revision of vascular procedure	201	Other Hepatobiliary & Pancreas Procedures.
3950	Angioplasty or atherectomy of noncoronary vessel	201	Other Hepatobiliary & Pancreas Procedures.
MDC 8—Diseases and Disorders of the Musculoskeletal System and Connective Tissue			
387	Interruption vena cava	233	Other Musculoskeletal System & Connective Tissue O.R. Procedures with CC.
387	Interruption vena cava	234	Other Musculoskeletal System & Connective Tissue O.R. Procedures without CC.
3950	Angioplasty or atherectomy of noncoronary vessel	233	Other Musculoskeletal System & Connective Tissue O.R. Procedures with CC.
3950	Angioplasty or atherectomy of noncoronary vessel	234	Other Musculoskeletal System & Connective Tissue O.R. Procedures without CC.
MDC 9—Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast			
8344	Other fasciectomy	269	Other Skin, Subcutaneous Tissue & Breast Procedures with CC.
8344	Other fasciectomy	270	Other Skin, Subcutaneous Tissue & Breast Procedures without CC.
8345	Other myectomy	269	Other Skin, Subcutaneous Tissue & Breast Procedures with CC.
8345	Other myectomy	270	Other Skin, Subcutaneous Tissue & Breast Procedures without CC.
8382	Muscle or fascia graft	269	Other Skin, Subcutaneous Tissue & Breast Procedures with CC.
8382	Muscle or fascia graft	270	Other Skin, Subcutaneous Tissue & Breast Procedures without CC.
MDC 10—Endocrine, Nutritional and Metabolic Diseases and Disorders			
387	Interruption vena cava	292	Other Endocrine, Nutritional, & Metabolic O.R. Procedures with CC.
387	Interruption vena cava	293	Other Endocrine, Nutritional, & Metabolic O.R. Procedures without CC.
5459	Other Lysis of Peritoneal adhesions	292	Other Endocrine, Nutritional, & Metabolic O.R. Procedures with CC.
5459	Other Lysis of Peritoneal adhesions	293	Other Endocrine, Nutritional, & Metabolic O.R. Procedures without CC.
MDC 11—Diseases and Disorders of the Kidney and Urinary Tract			
0492	Implantation or replacement of peripheral neuro-stimulator.	315	Other Kidney & Urinary Tract O.R. Procedures.
3821	Blood vessel biopsy	315	Other Kidney & Urinary Tract O.R. Procedures.
387	Interruption vena cava	315	Other Kidney & Urinary Tract O.R. Procedures.
3949	Other revision of vascular procedure	315	Other Kidney & Urinary Tract O.R. Procedures.
MDC 12—Diseases and Disorders Male Reproductive System			
387	Interruption vena cava	344	Other Male Reproductive System O.R. Procedures for Malignancy.
387	Interruption vena cava	345	Other Male Reproductive System O.R. Procedures Except for Malignancy.
8622	Excisional debridement of wound, infection, or burn	344	Other Male Reproductive System O.R. Procedures for Malignancy.
8622	Excisional debridement of wound, infection, or burn	345	Other Male Reproductive System O.R. Procedures Except for Malignancy.
MDC 13—Diseases and Disorders of the Female Reproductive System			
387	Interruption vena cava	365	Other Female Reproductive System O.R. Procedures.
MDC 16—Diseases and Disorders of the Blood, Blood Forming Organs, Immunological Disorders			
387	Interruption vena cava	394	Other O.R. Procedures of the Blood & Blood Forming Organs.

We did not receive any comments on the proposed movement of procedure codes from DRG 468. Accordingly, we are adopting, as final, the movement of the codes as outlined above.

b. Reassignment of Procedures Among DRGs 468, 476, and 477

We also annually review the list of ICD-9-CM procedures that, when in combination with their principal diagnosis code, result in assignment to DRGs 468, 476, and 477, to ascertain if any of those procedures should be reassigned from one of these DRGs to another of these DRGs based on average charges and length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting DRG assignment illogical. If we find these shifts, we would move cases to keep the DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data. Based on our review this year, we are not moving any procedures from DRG 468 to DRGs 476 or 477, from DRG 476 to DRGs 468 or 477, or from DRG 477 to DRGs 468 or 476.

c. Adding Diagnosis Codes to MDCs

Based on our review this year, we are not adding any diagnosis codes to MDCs.

13. Changes to the ICD-9-CM Coding System

As described in section II.B.1. of this preamble, the ICD-9-CM is a coding system that is used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD-9-CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD-9-CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-9-CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The ICD-9-CM Manual contains the list of valid diagnosis and procedure codes. (The ICD-9-CM Manual is

available from the Government Printing Office on CD-ROM for \$22.00 by calling (202) 512-1800.) The NCHS has lead responsibility for the ICD-9-CM diagnosis codes included in the *Tabular List* and *Alphabetic Index for Diseases*, while CMS has lead responsibility for the ICD-9-CM procedure codes included in the *Tabular List* and *Alphabetic Index for Procedures of the Manual*.

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA) (formerly American Medical Record Association (AMRA)), the American Hospital Association (AHA), and various physician specialty groups as well as physicians, medical record administrators, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2003 at public meetings held on May 17 and 18, 2001, and November 1 and 2, 2001, and finalized the coding changes after consideration of comments received at the meetings and in writing by January 8, 2002.

We described our plans to expedite the implementation of coding changes in the September 7, 2001 **Federal Register**, including moving the dates of the ICD-9-CM Coordination and Maintenance Committee to December and April of each year. We also established the possibility of implementing procedure codes discussed in the April meeting as part of the October update in the same year. This reduces the time for activating a new code from a minimum of 11 months to a minimum of 6 months.

Because the changes would not be included in the proposed rule published in the spring, the public would be given less opportunity to consider the merits of the proposals. Decisions from the spring meeting must be finalized by early June in order to be included in changes in the GROUPER software and be effective October 1. The addenda must also be published on the homepage and distributed to publishers

so that both paper versions of the ICD-9-CM code book and software applications can be ready in time for use by health care providers. Only those issues from the April meeting that could be quickly resolved and that received support from the public would be able to be included in the October addendum. Those that could not be quickly resolved would continue to be addressed as part of the addendum for October 1 of the next year.

The ICD-9-CM Coordination and Maintenance Committee met on April 18 and 19, 2002. Two code title issues discussed during that meeting were approved in time to be included in the Addendum of this final rule, to be effective October 1, 2002. These codes are new code 89.60 (Continuous intra-arterial blood gas monitoring) which is shown in Table 6B in the Addendum of this final rule, and revised code title 02.41 (Irrigation and exploration of ventricular shunt) which is shown in Table 6F in the Addendum of this final rule.

For a report of procedure topics discussed at the April 2002 meeting, see the Summary Report at: <http://www.cms.hhs.gov/medicare/icd9cm.asp>. This site also includes the Final Addendum for ICD-9-CM Procedures, which will be effective October 1, 2002.

Copies of the Coordination and Maintenance Committee minutes of the 2001 meetings can be obtained from the CMS home page at: <http://www.cms.gov/medicare/icd9cm.asp>. Paper copies of these minutes are no longer available and the mailing list has been discontinued. We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson; ICD-9-CM Coordination and Maintenance Committee; NCHS; Room 1100; 6525 Belcrest Road; Hyattsville, MD 20782. Comments may be sent by E-mail to: dfp4@cdc.gov.

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson; ICD-9-CM Coordination and Maintenance Committee; CMS, Center for Medicare Management, Purchasing Policy Group, Division of Acute Care; C4-08-06; 7500 Security Boulevard; Baltimore, MD 21244-1850. Comments may be sent by E-mail to: pbrooks@cms.hhs.gov.

The ICD-9-CM code changes that have been approved will become effective October 1, 2002. The new ICD-9-CM codes are listed, along with their DRG classifications, in Tables 6A and 6B (New Diagnosis Codes and New Procedure Codes, respectively) in the

Addendum to this final rule. As we stated above, the code numbers and their titles were presented for public comment at the ICD-9-CM Coordination and Maintenance Committee meetings. Both oral and written comments were considered before the codes were approved. In the proposed rule, we only solicited comments on the proposed DRG classification of these new codes.

For codes that have been replaced by new or expanded codes, the corresponding new or expanded diagnosis codes are included in Table 6A (New Diagnosis Codes) in the Addendum of this final rule. New procedure codes are shown in Table 6B. Diagnosis codes that have been replaced by expanded codes or other codes or have been deleted are in Table 6C (Invalid Diagnosis Codes). These invalid diagnosis codes will not be recognized by the GROUPER beginning with discharges occurring on or after October 1, 2002. Table 6C contains invalid diagnosis codes. There are no invalid procedure codes for FY 2002 (Table 6D). Revisions to diagnosis code titles are in Table 6E (Revised Diagnosis Code Titles), which also includes the DRG assignments for these revised codes. Revisions to procedure code titles are in Table 6F (Revised Procedure Codes Titles).

Comment: One commenter expressed concern about making procedure code changes discussed at the April ICD-9-CM Coordination and Maintenance Committee effective the following October. The commenter had concerns with the fact that these coding changes would not be discussed in the proposed rule, but would appear in the final rule. The commenter indicated that hospitals need time to comment on all proposed changes to the DRGs and to analyze changes for budgeting, train staff on coding changes, and implement software changes. The commenter also endorsed movements toward replacing ICD-9-CM with ICD-10-PCS and believed this would improve coded data. In addition, the commenter suggested that consideration be given to using Alpha-numeric HCPCS codes to report the use of drugs, supplies, and devices used for inpatients, instead of trying to make ICD-9-CM serve this purpose.

Response: We discussed the issue of consideration of coding changes at the April meeting of the Committee in the final rule on Payment for New Medical Services and New Technologies Under the Acute Care Hospital Inpatient Prospective Payment System published in the **Federal Register** on September 7, 2001 (66 FR 46902). We were

responding to section 533 of Public Law 106-554, which provided for expediting the incorporation of new services into the coding system. While we recognize the commenter's concern, we also are responding to repeated requests to expedite our process of updating codes. We will carefully evaluate requests for new codes that are discussed at the April ICD-9-CM Coordination and Maintenance Committee to determine which codes can and should be included in the addendum on ICD-9-CM effective October of each year. We encourage the commenter to continue to participate in the process by attending these public meetings and offering its opinions.

On the issue of the movement to ICD-10-PCS and the possibility of using HCPCS codes for inpatient reporting, we note this issue is currently under review by the National Committee on Vital and Health Statistics (NCVHS). This committee advises the Secretary on coding standards issues under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The committee is currently conducting public meetings on the issues raised by this commenter. We will defer issues involving changes to the HIPAA standards to the NCVHS. For more information on this committee, please see its web site at: <http://www.ncvhs.hhs.gov/>.

14. Other Issues

In addition to the specific topics discussed in section II.B.1. through 13. of this final rule, we addressed a number of other DRG-related issues in the May 9, 2002 proposed rule. In the proposed rule, we did not propose any changes to the DRGs relating to the issues. Below is a summary of the issues that were addressed, any public comments we received, and our responses to those comments.

a. Intestinal Transplantation

We examined our data to determine whether it is appropriate to add a new intestinal transplant DRG. Our data revealed that nine intestinal transplantation cases were reported by two facilities. Of the nine cases, two cases involved a liver transplant during the same admission and, therefore, would be assigned to DRG 480 (Liver Transplant). As we stated in the proposed rule, we do not believe that the remaining seven cases provide a sufficient number to warrant the creation of a new intestinal transplant DRG.

Comment: Commenters supported the proposal not to create a separate new DRG for intestinal transplants and

pointed out that this procedure is not being widely performed.

Response: We will continue to monitor intestinal transplantation cases to determine whether it may be appropriate in the future to establish a new DRG for the intestinal transplant procedure.

b. Myasthenia Gravis

Myasthenia Gravis is an autoimmune disease manifested by a syndrome of fatigue and exhaustion of the muscles that is aggravated by activity and relieved by rest. The weakness of the muscles can range from very mild to life-threatening.

This disease is classified to ICD-9-CM diagnosis code 358.0 and is assigned to DRG 12 (Degenerative Nervous System Disorders). Myasthenia Gravis in crisis patients is being treated with extensive plasmapheresis. We received a request to analyze the charges associated with Myasthenia Gravis in crisis patients receiving plasmapheresis to determine whether DRG 12 is an equitable DRG assignment for these cases. We are currently unable to differentiate between the mild and severe forms of this disease because all types are classified to code 358.0. Therefore, we requested the NCHS to create a new diagnosis code for Myasthenia Gravis in crisis so that we can uniquely identify these cases to ensure the DRG assignment is appropriate.

Comment: Commenters supported the creation of a new diagnosis code so that Myasthenia Gravis in crisis patients can be uniquely identified and the mild and severe forms of the disease is distinguished.

Response: This topic was addressed at the April 18, 2002 ICD-9-CM Coordination and Maintenance Committee meeting. NCHS proposed two new codes to capture Myasthenia Gravis not in crisis and Myasthenia Gravis in crisis. If the Committee approves these two codes, they would not become effective until October 1, 2003. At that point, we would be able to assess the charges associated with Myasthenia Gravis in crisis patients receiving plasmapheresis.

c. Cardiac Mapping and Ablation

In the August 1, 2001 final rule (66 FR 39840), in response to a comment received, we agreed to continue to evaluate DRGs 516 (Percutaneous Cardiovascular Procedure with Acute Myocardial Infarction (AMI)), 517 (Percutaneous Cardiovascular Procedure with Coronary Artery Stent without AMI), and 518 (Percutaneous Cardiovascular Procedure without

Coronary Artery Stent or AMI) in MDC 5. For the proposed rule, we reviewed code 37.26 (Cardiac electrophysiologic stimulation and recording studies), code 37.27 (Cardiac mapping), and code 37.34 (Catheter ablation of lesion or tissues of heart). The commenter had recommended that CMS either create a separate DRG for cardiac mapping and ablation procedures, or assign codes 37.27 and 37.34 to DRG 516 after retitling the DRG. We have reviewed FY 2001 MedPAR data on these specific codes. Over 97 percent of cases with these codes were assigned to DRG 518 and had average charges of \$1,741 below the average for all cases in the DRG. Therefore, the data do not support making any DRG changes for these procedure codes.

We received one comment in support of our proposal not to make DRG changes to the cardiac mapping and ablation codes. Accordingly, in this final rule, we will not make any changes relating to the DRG assignment of codes 37.20, 37.26, and 37.34

d. Aortic Endograft

In the August 1, 2001 final rule (66 FR 39841), we responded to a comment concerning the placement of aortic endografts in DRG 110 (Major Cardiovascular Procedures with CC) and DRG 111 (Major Cardiovascular Procedures without CC). The commenter noted that the cost of the device alone is greater than the entire payment for DRG 111 and recommended that these cases be assigned specifically to DRG 110. Our response at that time was that DRGs 110 and 111 are paired DRGs, differing only in the presence or absence of a CC.

We reviewed the MedPAR data again for FY 2001 using the following criteria: All cases were either in DRG 110 or 111, had a principal diagnosis of 441.4 (Abdominal aneurysm without mention of rupture), and included procedure code 39.71 (Endovascular implantation of graft in abdominal aorta). Our conclusion is that the majority of aneurysm cases are already grouped to DRG 110, where they are appropriately compensated. Therefore, we did not propose to assign cases without CCs from DRG 111 to DRG 110. We reiterate that hospitals are responsible for coding their records completely and for recording and submitting all relevant diagnosis and procedure codes that have a bearing on the current admission (in particular, any secondary or additional diagnosis codes that may be recognized by the GROUPER software as codes describing complications or comorbidities associated with a case).

Comment: One commenter recommended a new DRG due to the significant costs associated with the device.

Response: The commenter submitted no data that would cause us to question our findings described above. Therefore, in this final rule, we are not changing the current DRG assignment of procedure code 39.71. e. Platelet Inhibitors.

In the August 1, 2001 final rule (66 FR 39840), we addressed a commenter's concern that modifications to MDC 5 involving percutaneous cardiovascular procedures would fail to account for the use of GP IIB-IIIa platelet inhibiting drugs for cases with acute coronary syndromes. GROUPER does not recognize procedure code 99.20 (Injection or infusion of platelet inhibitor) as a procedure. Therefore, its presence on a claim does not affect DRG assignment. We agreed to continue to evaluate this issue.

For the May 9, 2002 proposed rule, we reviewed cases in the FY 2001 MedPAR file for DRG 121 (Circulatory Disorders with AMI and Major Complication, Discharged Alive), DRG 122 (Circulatory Disorders with AMI without Major Complication, Discharged Alive) and DRGs 516, 517, and 518. We looked at all cases in these DRGs containing procedure code 99.20 by total number of procedures and by average charges. There were a total of 73,480 cases where platelet inhibitors were administered, with 70,216 of these cases in DRGs 516, 517, and 518. The average charges for platelet inhibitor cases in these three DRGs are actually slightly below the average for all cases in the respective DRGs. Therefore, we believe these cases are appropriately placed in the current DRGs, and we did not propose any changes to the assignment of the procedure code 99.20.

We received one comment in support of maintaining the current DRG assignments of code 99.20. Therefore, in this final rule, we are not making any changes to the DRG assignments of code 99.20.

f. Drug-Eluting Stents

The drug-eluting stent technology has been developed to combat the problem of restenosis of blood vessels previously treated for stenosis. The drug is coated on a stent with a special polymer, and after the stent is placed in the vessel, the drug is slowly released into the vessel wall tissue over a period of 30 to 45 days. The drug coating on the stent is intended to prevent the build-up of scar tissue that can narrow the reopened artery.

In Table 6B of the Addendum to this final rule, we list a new procedure code 36.07 (Insertion of drug-eluting coronary artery stents(s)) that will be effective for use October 1, 2002. We also are adding code 00.55 (Insertion of drug-eluting noncoronary artery stent).

A manufacturer of this technology asserted that this technology is significantly more costly than other technologies currently assigned to DRG 517 (Percutaneous Cardiovascular Procedure with Coronary Artery Stent without AMI) (average charges of \$29,189 compared to average charges of \$22,998). The manufacturer requested that code 36.07 be assigned to DRG 516 (Percutaneous Cardiovascular Procedure with Acute Myocardial Infarction (AMI)) even without the presence of AMI.

In addition, the manufacturer argued that this technology should be given preferential treatment because it will fundamentally change the treatment of multivessel disease. Specifically, the manufacturer stated that due to the absence of restenosis in patients treated with the drug-eluting stents based on the preliminary trial results, bypass surgery may no longer be the preferred treatment for many patients.¹ The manufacturer believes lower payments due to the decline in Medicare bypass surgeries will offset the higher payments associated with assigning all cases receiving the drug-eluting stent to DRG 516.

The FDA has not yet approved this technology for use. In the May 9, 2002 proposed rule, we specifically solicited comments on our proposal to treat the new codes cited above consistent with the current DRG assignment for coronary artery stents. We also stated that if the technology is approved by the FDA and further evidence is presented to us regarding the clinical efficacy and the impact that this technology has on the treatment of multivessel disease, we may reassign this code to another DRG or reassess the construct of all affected DRGs.

Comment: Several commenters supported the development of new ICD-9-CM codes 36.07 and 00.55 for drug-eluting stents, citing the need for identification of this new technology. Several commenters supported the creation of new ICD-9-CM codes in order to ensure this technology would receive payment under Medicare.

Response: We created two new ICD-9-CM codes for use with cases

¹ "Comparison of Coronary-Artery Bypass Surgery and Stenting for the Treatment of Multivessel Disease," Serruys, P.W., Unger, F., et al., *The New England Journal of Medicine*, April 12, 2001, Vol. 344, No. 15, p. 1117.

involving discharges occurring on or after October 1, 2002. These codes can be found in Table 6B. "New Procedure Codes" in the Addendum of this final rule. However, we emphasize that it is not necessary to assign new technologies a new ICD-9-CM code in order for Medicare payment to commence. In the absence of a new code, technologies are assigned to the nearest similar existing code and, consequently, to the relevant DRG for payment.

Comment: Numerous comments opposed our proposed DRG assignment of code 36.07 to DRG 517. One commenter noted that, while this technology is not yet approved, it has shown promise to significantly advance the treatment of coronary artery disease, and encouraged CMS to consider the available data to determine the most appropriate paying DRG. This commenter supported the reassignment of code 36.07 to another DRG or, if necessary, the modification of all affected DRGs, once verifiable data on the costs associated with drug-eluting stents become available.

Many of the commenters who supported higher payment for this technology were clinical practitioners and hospitals who expressed great anticipation for the potential benefits of this technology. In addition, commenters referred to the likelihood that, once these new drug-eluting stents are approved, patients would demand to have them inserted. This demand would put tremendous financial strain on hospitals.

Commenters also argued there should be long-term cost savings to the Medicare program and the health system generally from this technology after approval by the FDA. Specifically, if dramatically fewer patients require restenting, savings will result from fewer repeat angioplasty procedures. Also, to the extent bypass surgeries are also reduced (as suggested by the article footnoted above), savings will result from that outcome as well.

Response: We note that, at this point, the FDA has not approved this technology for general use. However, we also note that public presentation of the results from recent clinical trials have found virtually no in-stent restenosis in patients treated with the drug-eluting stent. Therefore, we recognize the potentially significant impact this technology may conceivably have on the treatment of coronary artery blockages.

As we have previously stated, new technology is generally assigned to the same DRG as the predecessor technologies. In this way, hospitals can receive payment immediately for the

new technology. As use of the new technology diffuses among hospitals, we have gradually and largely automatically recalibrated DRG payment rates based on hospital claims data to reflect increasing or decreasing costs of cases assigned to the DRG. Generally, it takes 2 years for claims data to be reflected in the DRG weights.

Section 533 of Public Law 106-554 added sections 1886(d)(5)(K) and (d)(5)(L) to the Act (as implemented by §§ 412.87 and 412.88) to reduce the time needed for the DRG system to recognize the higher costs of new technologies that meet certain criteria (see section II.D. of this final rule). However, drug-eluting stents did not meet the cost threshold criterion. Therefore, we proposed to assign cases involving code 36.07 to DRG 517. Although this DRG assignment would be consistent with our prior practice of assigning new technology to the same DRGs to which its predecessor technologies were assigned, further consideration of this issue persuades us that a different approach is needed, given the extraordinary circumstances in this particular instance.

We are concerned that, if the FDA does approve this technology and the predictions of its rapid, widespread use are accurate, this action will result in a significant strain on hospital financial resources. In particular, we are concerned that the higher costs of this technology would create undue financial hardships for hospitals due to the high volume of stent cases and the fact that a large proportion of these cases could involve the new technology soon after FDA approval. Therefore, in this final rule we are creating two new DRGs that parallel existing DRGs 516 and 517, to reflect cases involving the insertion of a drug-eluting coronary artery stent as signified by the presence of code 36.07: DRG 526 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with AMI); and DRG 527 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without AMI). We understand the earliest date that a decision from the FDA is anticipated is late 2002. To further ensure that payments for the new DRGs 526 and 527 will not be made prior to FDA approval, we will activate these DRGs effective for discharges occurring on or after April 1, 2003. If the FDA approves the use of drug-eluting stents prior to April 1, 2003, cases coded with procedure code 36.07 will be paid using the DRG relative weights for DRG 517. New DRGs 526 and 527 will be temporary DRGs. By creating separate new DRGs, we are able to ensure that higher payments will only be made after a positive decision by the

FDA. We expect that when claims data are available that reflect the use of these stents, we will combine drug-eluting stent cases with other cases in DRGs 516 and 517.

Although one manufacturer of this technology submitted data to us that included charges, hospital provider numbers, and admission and discharge dates on the Medicare patients for whom hospital bills were collected under the trial in order to demonstrate the higher average charges of cases included in the trial, much of the data submitted to us included only estimated charges for the new technology. Therefore, it was necessary to undertake several calculations to establish the DRG relative weights for these two new DRGs. First, based on prices in countries where drug-eluting stents are currently being used, and the average price of currently available stents, we calculated a price differential of approximately \$1,200. Assuming average hospital charge markups for this technology (based on weighted average cost-to-charge ratios), the anticipated charge differential between old and new stents would be approximately \$2,664 per stent. However, we recognize that some cases involve more than one stent. Using an average of 1.5 stents per procedure, the net estimated incremental charge for cases that would receive a drug-eluting stents is \$3,996.

In order to accurately determine the DRG relative weights for these two new DRGs relative to all other DRGs, we must also estimate the volume of cases likely to occur in them among discharges occurring on or after April 1, 2003 and by September 30, 2003. To approximate the number of cases that would likely receive the drug-eluting stent between April 1, 2003 and September 30, 2003 (and thus would be assigned to new DRGs 526 and 527), we first identified cases in DRGs 516 and 517 with procedure code 36.06 (Insertion of non-drug-eluting coronary artery stent). Of these cases, we estimated what percentage would be likely to receive the drug-eluting stent after April 1, 2003. The manufacturer estimated that as many as 43 percent of current stent patients will receive drug-eluting stents during FY 2003. However, this estimate assumes 9 months of sales of the new stents during FY 2003, from January to September. Because these two new DRGs will only be valid for 6 months during FY 2003, from April through September, we estimated that 21.5 percent of all stent cases will be assigned to new DRGs 526 and 527 (43 percent of stent cases for 6 months instead of 9 months).

In determining the DRG relative weights, we assumed that 21.5 percent of coronary stent cases (those with code 36.06) from DRGs 516 and 517 would be reassigned to new DRGs 526 and 527 (with code 36.07), and the charges of these cases would be increased \$3,996 per case, to approximate the higher charges associated with the drug-eluting stents in DRGs 526 and 527. The relative weights for DRGs 516 and 517 are calculated based on the charges of the cases estimated to remain in these two DRGs.

We note that this unprecedented approach is in response to the unique circumstances surrounding the potential breakthrough nature of this technology. We anticipate that the vast majority of new technologies in the future will continue to be routinely incorporated into the existing DRGs.

New DRG 526 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent With AMI) will have the following principal diagnoses:

- 410.01, Acute myocardial infarction, anterolateral wall, initial episode of care.
 - 410.11, Acute myocardial infarction, other anterior wall, initial episode of care.
 - 410.21, Acute myocardial infarction, inferolateral wall, initial episode of care.
 - 410.31, Acute myocardial infarction, inferoposterior wall, initial episode of care.
 - 410.41, Acute myocardial infarction, inferior wall, initial episode of care.
 - 410.51, Acute myocardial infarction, other lateral wall, initial episode of care.
 - 410.61, True posterior wall infarction, initial episode of care.
 - 410.71, Subendocardial infarction, initial episode of care.
 - 410.81, Acute myocardial infarction of other specified sites, initial episode of care.
 - 410.91, Acute myocardial infarction, unspecified site, initial episode of care.
- And operating room procedures:
- 35.96, Percutaneous valvuloplasty.
 - 36.01, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy without mention of thrombolytic agent.
 - 36.02, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with mention of thrombolytic agent.
 - 36.05, Multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent.

- 36.09, Other removal of coronary artery obstruction.
- 37.34, Catheter ablation of lesion or tissues of heart.

Or nonoperating room procedures:

- 37.26, Cardiac electrophysiologic stimulation and recording studies.
- 37.27, Cardiac mapping.
- And nonoperating room procedure:
- 36.07, Insertion of drug-eluting coronary artery stent(s).

The principal diagnosis will consist of any principal diagnosis in MDC 5 except AMI:

- 410.01, Acute myocardial infarction, anterolateral wall, initial episode of care.
 - 410.11, Acute myocardial infarction, other anterior wall, initial episode of care.
 - 410.21, Acute myocardial infarction, inferolateral wall, initial episode of care.
 - 410.31, Acute myocardial infarction, inferoposterior wall, initial episode of care.
 - 410.41, Acute myocardial infarction, inferior wall, initial episode of care.
 - 410.51, Acute myocardial infarction, other lateral wall, initial episode of care.
 - 410.61, True posterior wall infarction, initial episode of care.
 - 410.71, Subendocardial infarction, initial episode of care.
 - 410.81, Acute myocardial infarction of other specified sites, initial episode of care.
 - 410.91, Acute myocardial infarction, unspecified site, initial episode of care.
- And operating room procedures:
- 35.96, Percutaneous valvuloplasty.
 - 36.01, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy without mention of thrombolytic agent.
 - 36.02, Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with mention of thrombolytic agent.
 - 36.05, Multiple vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent.
 - 36.09, Other removal of coronary artery obstruction.
 - 37.34, Catheter ablation of lesion or tissues of heart.
- Or nonoperating room procedures:
- 37.26, Cardiac electrophysiologic stimulation and recording studies.
 - 37.27, Cardiac mapping.
- And nonoperating room procedure:
- 36.07, Insertion of drug-eluting coronary artery stent(s).

Comment: One commenter expressed concern that this technology will be used to treat lesions that are not clinically indicated. This commenter suggested that there should be clear language stating that drug-eluting stents should only be used in patients who are symptomatic from coronary artery disease as documented by noninvasive stress tests and imaging to locate the ischemia.

Response: We appreciate the commenter's concern that this new technology be used only where it is clinically indicated. We note that our treatment of this technology should in no way be construed to circumvent the ongoing FDA review. We expect that the technology, if approved, would be used in accordance with any labeling guidelines issued by the FDA, and we reserve the right to evaluate the need for Medicare coverage limitations or restrictions in the future.

Comment: One commenter applauded our recognition of the potential advance in peripheral vascular care by creating a code for noncoronary artery stents, code 00.55 (Insertion of drug-eluting noncoronary artery stent(s)). However, the commenter indicated it could not discern from Table 6B (67 FR 31630) the DRG to which code 00.55 was assigned.

Response: Our usual practice is to assign a new code to the DRG to which the predecessor code had been assigned. For example, in 1995, when we added additional fourth digits to 60.2 (Transurethral prostatectomy) and created 60.21 (Transurethral (ultrasound) guided laser induced prostatectomy (TULIP)) and 60.29 (Other Transurethral prostatectomy), we assigned the two new codes to the DRGs in which 60.2 had been located. (In version 12.0 of the GROUPEP, those DRGs were 306 and 307 and DRG 336 and 337; the two newer codes continue to be assigned to the same DRGs today.) We have followed this precedent with code 00.55, which is patterned after code 39.90 (Insertion of non-coronary artery stent or stents). Code 39.90 is not a code recognized by the GROUPEP software as a procedure code that causes DRG assignment, and therefore it is not assigned to a DRG or DRGs by itself. The GROUPEP will recognize the main procedure in which a stent is inserted in order to make the DRG assignment for that case. We recognize that insertion of stents in noncoronary vessels has the potential to occur in many MDCs and DRGs. We will monitor the new stent code in noncoronary vessels in our MedPAR data to determine if the DRG placement in which it is reported is appropriate.

g. Cardiac Resynchronization Therapy

Cardiac resynchronization therapy for heart failure provides strategic electrical stimulation to the right atrium, right ventricle, and left ventricle, in order to coordinate ventricular contractions and improve cardiac output. This therapy includes cardiac resynchronization therapy pacemakers (CRT-P) and cardiac resynchronization therapy defibrillators (CRT-D). While similar to conventional pacemakers and internal cardioverter-defibrillators, cardiac resynchronization therapy is different because it requires the implantation of a special electrode within the coronary vein, so that it can be attached to the exterior wall of the left ventricle.

We received a recommendation that we assign implantation of CRT-D (code 00.51, effective October 1, 2002) to either DRG 104 (Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization) or DRG 514 (Cardiac Defibrillator Implant With Cardiac Catheterization). Currently, defibrillator cases are assigned to either DRG 514 (Cardiac Defibrillator Implant With Cardiac Catheterization) or DRG 515 (Cardiac Defibrillator Implant Without Cardiac Catheterization). DRG 514 has a higher relative weight than DRG 515. The manufacturer argued that the change should be made because the current DRG structure for cardioverter-defibrillator implants does not recognize the significant amount of additional surgical resources required for cases involving patients with heart failure.

The recommendation also supported assigning new code 00.50 (Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system [CRT-P]) to DRG 115 (Permanent Cardiac Pacemaker Implantation With AMI, Heart Failure, or Shock, or AICD Lead or Generator Procedure). Currently, pacemaker implantation procedures are assigned to either DRG 115 or DRG 116 (Other Permanent Cardiac Pacemaker Implant). DRG 115 has the higher relative weight. Because DRG 115 recognizes patients with heart failure, the manufacturer believed CRT-P cases would be appropriately classified to DRG 115.

We proposed to assign code 00.51 to DRG 514 or 515 and to assign code 00.50 to DRG 115 and 116. However, we solicited comments on these proposed DRG assignments and indicated that we would carefully consider any relevant evidence about the clinical efficacy and costs of this technology.

Comment: Numerous commenters responded to our statement that we would further consider evidence on the costs and clinical efficacy of the cardiac

resynchronization technology. Commenters noted that, on average, patients with moderate to severe heart failure (New York Heart Class III/IV), for whom the CRT is indicated, are more physically compromised and need the support of additional personnel such as physical assistants and clinical heart failure coordinators. Data were submitted showing that heart failure cases have significantly longer average lengths of stay than average stays for other cases. These cases also have higher average charges (approximately \$11,000 to \$13,000 higher, according to one commenter). The commenters acknowledged that DRG 115 does specifically account for heart failure cases, but noted that DRGs 514 and 515 do not.

Commenters also argued there are additional costs associated with the additional surgical supplies required to perform these procedures (as well as the price differential of the new technology itself). Examples of supplies include a special left ventricular coronary sinus lead, a special pulse generator device, and a special electrical lead. One manufacturer estimated the incremental difference in the charges of the device and the additional surgical supplies to be \$23,500.

Commenters further noted the additional surgical procedure time associated with CRTs. They noted that the implant procedure itself is much more complex than a conventional pacemaker or implanted cardioverter defibrillator, and generally requires additional staff, anesthesia, and other specialized services and supplies. The insertion of the left ventricular lead is estimated to require an additional 2 hours beyond a conventional procedure. Commenters pointed out that typically a venogram is required to navigate the coronary venous system. The additional time and resources were estimated to increase costs to the hospitals by \$7,500.

Finally, commenters also cited data and anecdotal evidence to demonstrate the clinical benefits of this technology. The commenters noted that FDA approved CRT-D on May 2, 2002, which provides further evidence of the clinical efficacy of this technology. One commenter provided information to show that CRT-D improves peak oxygen uptake, translating to an increased ability to perform activities of daily living. Another commenter noted that pacing therapy offers the potential to increase blood pressure and heart rate.

On the basis of these higher costs and clinical improvements, these commenters generally recommended that CRT-Ds should be assigned to DRG 104. This DRG has a higher relative

payment weight than either DRGs 514 or 515 (7.9615, compared to 6.3288 and 5.0380, respectively, based on the FY 2003 proposed DRG weights). One commenter suggested that if CRT-D cases are not assigned to DRG 104, they should only be assigned to DRG 514, not DRG 515. Several commenters suggested that CRT-Ps be assigned only to DRG 115, and not to DRG 116, since DRG 115 is the higher paying DRG. Other commenters suggested that all CRT-Ps be assigned to DRG 515 since DRG 515 pays more.

One commenter suggested that CRT-Ds are more clinically coherent to cases now assigned to DRG 104 based on: (1) The similarity of the diagnosis (for example, congestive heart failure); and (2) the similarities in clinical procedures used to implant a left ventricular lead and other cardiac catheterizations included in DRG 104. The commenter also suggested that the operating room preparation and procedure time for CRT-D cases was similar to that for other major cardiovascular procedures included in DRG 104, which supports the commenter's contention that CRT-Ds are more clinically consistent with DRG 104 than DRG 514 and 515.

Several commenters, including a national and a State hospital association, supported the assignment of new code 00.51 to DRG 514 or 515. Some commenters also supported the assignment of new code 00.50 to DRG 115 and DRG 116. The commenters added that cardiac resynchronization therapy is a new technology that recently received FDA approval and is still not widely used in hospitals in the United States. The commenters indicated that even though there is limited information at this time with regard to the clinical efficacy and costs of these devices, the technology seems to be similar to pacemakers and defibrillators, so the proposed DRG grouping is logical.

Response: We have carefully evaluated the information provided to us by the commenters. With respect to the cost data provided, we note that it is our previously stated preference to review actual data reflecting the total costs per case from patients treated with a particular new technology. Because the DRG payment is intended to cover all of the care provided during the course of an inpatient hospitalization, it is necessary to evaluate the impact a new technology may have on other aspects of patients' hospitalization. For example, many new technologies allow patients to be discharged sooner, actually reducing the total costs of the stay. While there is no indication that

this is the case with the CRT-D technology, we are unable to make an assessment based on the segregated data that were provided.

With respect to the suggestion that CRT-D cases should be assigned to DRG 104, we note that the DRG system groups cases that are similar clinically and in terms of costs. DRG 104 includes procedures performed on cardiac valves such as valve replacement and repair. Our clinical advisors disagree with the suggestion that the implantation of a CRT with or without defibrillation is clinically related or similar to procedures such as valve repair or replacement, which are assigned to DRG 104. We believe that, based on the nature and function of the devices, they are more appropriately classified as either pacemakers for the CRT-P or implantable cardioverter-defibrillators (ICDs) for the CRT-D devices. The additional lead is not, in our view, sufficient justification for classifying the CRT-Ds differently from all other defibrillators.

Furthermore, although chronic heart failure, for which these CRTs are used, is a common diagnosis, the etiology of the heart failure may vary significantly. Heart failure due to a faulty valve may be treated with valvuloplasty or valve replacement, and would be classified to DRG 104. On the other hand, heart failure due to ischemic events, such as a myocardial infarction, usually requires a completely different therapeutic approach involving other DRG assignments. Therefore, we do not believe it would be appropriate to classify cases receiving CRT-Ds to DRG 104.

With respect to the fall-back recommendation of the commenter that, if CRT-D cases are not assigned to DRG 104, they should all be assigned to DRG 514, we considered and rejected this suggestion. We note that a fundamental assumption underlying the DRGs is that the hospital has the responsibility for deciding what technology and process to employ in treating a particular type of patient. As hospitals in the aggregate make treatment decisions, these decisions are reflected in the DRG payment weights. This allows the payment rates to evolve in response to changing practice patterns.

The decision to treat CRT-D technology similarly to existing defibrillator technology is affected by our opinion that substantial improvement in health outcome benefits of adding the cardioverter-defibrillator component have not been fully established through clinical research. There are no published articles that have shown an improvement in survival

from CRT. Although we appreciate the information provided by the commenters in this regard, we note there is not a significant body of evidence that CRT-D technology will supplant existing treatments for large numbers of patients. Because the DRG payment system is an average-based system wherein hospitals are expected to offset the higher costs of some cases with below-average costs in others, we anticipate that hospitals will be able to adequately finance this new technology as it is utilized. To the extent hospitals move to adopt this technology more widely over time, appropriate adjustments will be reflected in the DRG weights.

With respect to the recommendation that all CRT-P cases be assigned to DRG 115, CRT-Ps are inserted into patients with congestive heart failure. Therefore, when the code for CRT-P is reported in a patient with congestive heart failure, the case will be assigned to DRG 115. Only if the CRT-P were inserted in a patient who does not have congestive heart failure would the case be assigned to DRG 116. Since all the commenters agree that only patients with congestive heart failure would be candidates for the CRT-P, the end result will be that all of these cases would be assigned to DRG 115 as the commenters recommended. With respect to the recommendation that all CRT-Ps be assigned to DRG 515, our response is the same as for rejecting the assignment of CRT-Ds to DRG 515. Assignment of CRT-Ps to DRG 515 is not clinically appropriate.

Accordingly, we are adopting as final our proposed classification of code 00.50 to DRGs 115 and 116, and code 00.51 to DRGs 514 and 515. These changes will be effective for discharges occurring on or after October 1, 2002.

Comment: Many commenters mentioned that when the CRT-Ds are inserted, a coronary sinus venogram is often performed. The commenters stated that a venogram is a procedure that is similar to an arteriogram, which is classified as a non-O.R. procedure that affects the DRG assignment in some cases. The commenters stated that the additional time and resources of the venogram for a CRT-D should be accounted for by assignment of these cases to DRG 104.

Response: Coronary arteriograms and angiocardiograms do effect the DRG assignment in some cases. Arteriograms and angiograms of other sites that are not of the heart do not affect the DRG assignment. Venograms are not currently on the list of non-O.R. procedures that affect the DRG assignment. While the commenters are not suggesting that we add venograms to

the list of non-O.R. procedures that affect the DRG assignment, they are recommending that the comparison of venograms to angiocardiograms be used as a justification for assigning CRT-Ds to DRG 104. Our medical consultants advise us that venograms are not as difficult to perform as are the coronary arteriograms and angiocardiograms. Venograms also have fewer associated risks than coronary arteriograms and angiocardiograms. Therefore, we would not reclassify venograms and make them affect the DRG assignment. In short, we do not believe that the performance of a venogram is justification for moving CRT-Ds to DRG 104.

h. Hip and Knee Revisions

We received a request to consider assigning hip and knee revisions (codes 81.53 and 81.55) out of DRG 209 (Major Joint and Limb Reattachment Procedures of Lower Extremity) because these revisions are significantly more resource intensive and costly than initial insertions of these joints.

We examined claims data and concluded that, while the charges for the hip and knee revision cases were somewhat higher than other cases within DRG 209, they do not support the establishment of a separate DRG.

Comment: Two commenters addressed this issue. One commenter stated that additional data review was needed to determine the variation in charges and length of stay to determine if this recommendation should be pursued. Another commenter stated that using charge data is incorrect. Hospitals are under increased pressure and scrutiny to keep their charges low and would not increase the charges of the revision prosthetic because it does not influence the amount of payment received. The commenter suggested that revisions of the hip and knee procedures should have their own DRG.

Response: Hospital charges have been the basis for recalibration of the DRG weights since FY 1986. Therefore, it is in the hospitals' best interest to submit accurate billing data. We utilize charge data in our analysis of the DRGs to ensure that each DRG contains patients with a similar pattern of resource intensity. To the extent that the markup of charges over cost varies from one particular device or procedure to another, the relative weights will be impacted. However, due to the relativity of the DRG weights, a low markup associated with one device or procedure will be offset by relatively higher markups associated with another device or procedure, leading to higher relative weights, and thus higher payments, for the latter device or procedure.

i. Multiple Level Spinal Fusions

We received correspondence suggesting that we create new spinal fusion DRGs that differentiate by the number of discs that are fused in a spinal fusion. The correspondents indicated that the existing ICD-9-CM codes do not identify the number of discs that are fused. Codes were modified for FY 2002 to clearly differentiate between fusions and refusions, and new codes were created for the insertion of interbody spinal fusion device (84.51), 360 degree spinal fusion, single incision approach (81.61), and the insertion of recombinant bone morphogenetic protein (84.52) (66 FR 39841 through 39844).

ICD-9-CM codes have not historically been used to differentiate among cases by the number of repairs or manipulations performed in the course of a single procedure. However, we explored the possibility of creating codes to differentiate cases by the number of discs fused during a spinal fusion procedure at the April 18 and 19, 2002 meetings of the ICD-9-CM Coordination and Maintenance Committee. Because the topic proved to be quite challenging and will require additional discussion, the Committee will consider it further at its scheduled December 5 and 6, 2002 meeting.

We also note that DRGs generally do not segregate cases based on the number of repairs or devices that occur in the course of a single procedure. For instance, DRGs are not split based on the number of vessels bypassed in cardiac surgery, nor are they split based on the number of cardiac valves repaired. Therefore, we did not propose DRG changes for multiple level spinal fusions in the May 9, 2002 proposed rule.

Comment: Commenters representing national and state hospital associations supported the proposal to not make DRG changes for multiple level spinal fusions at this time. The commenters agreed that ICD-9-CM historically has not been used to differentiate among cases by the number of repairs or manipulations performed during a single procedure. Also, the commenters wrote that developing a coding methodology for multiple level spinal fusions will require careful consideration because it will be introducing a new concept into ICD-9-CM coding. The commenters offered to work with CMS to examine whether such a methodology could be developed in the future.

One commenter urged CMS to carefully examine the issue of providing separate codes and payment for

multiple level spinal procedures. The commenter stated that increased costs were incurred in this type of surgery and may warrant recognition within the DRGs.

Response: We appreciate the comments on what has evolved as a challenging coding issue. We look forward to working with the commenter and other groups as we attempt to develop an efficient way to capture multilevel spinal fusions. The topic will be discussed at the next meeting of the ICD-9-CM Coordination and Maintenance Committee, which will be held on December 5 and 6, 2002. The agenda for this meeting will be posted in November 2002 at: www.cms.hhs.gov/medicare/icd9cm.asp. Once new codes are developed, we will evaluate the DRG assignments.

j. Open Wound of the Hand

We received a recommendation that we move code 882.0 (Open Wound of Hand Except Finger(s) Alone Without Mention of Complication) from its current location in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) under DRGs 280 through 282 (Trauma to the Skin, Subcutaneous Tissue and Breast Age >17 with CC, Age >17 without CC, and Age 0-17, respectively) into MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) under DRGs 444 through 446 (Traumatic Injury Age >17 with CC, Age >17 without CC, and Age 0-17, respectively).

In examining our data, we found relatively few cases with code 882.0. These cases had charges that were less than the average charges for DRGs to which they are currently assigned. The data do not support a DRG change. Our medical consultants also believe that the cases are appropriately assigned to DRGs 280 through 282.

We received comments in support on our proposed decision that the current DRG assignments for code 882.0 are appropriate. Accordingly, in this final rule we are not making any modifications of the DRG assignments for cases with code 882.0 at this time.

k. Cavernous Nerve Stimulation

As discussed in the August 1, 2001 final rule (66 FR 39845), we reviewed data in MDC 12 (Diseases and Disorders of the Male Reproductive System) to look specifically for code 89.58 (Plethysmogram) in DRG 334 (Major Male Pelvic Procedures with CC) and DRG 335 (Major Male Pelvic Procedures without CC).

Our data show that very few (six) of these procedures were reported on FY 2001 claims. It is not clear whether the

small number reflects the fact that the procedure is not being performed, the ICD-9-CM code is not recorded, or the code is recorded but it is not in the top six procedures being performed.

However, in all six cases where this procedure was performed, it occurred in conjunction with radical prostatectomy, so we are confident that these cases are consistent with the DRGs to which they have been assigned. Therefore, we did not propose any DRG assignment changes to procedures code 89.58 or any changes to DRGs 334 and 335.

We received one comment in support of our proposal not to change the DRG assignment of code 89.58 or DRGs 334 and 335. Accordingly, in the final rule we are making no changes to DRGs 334 and 335 with regard to procedure code 88.58. We anticipate that procedure code 89.58 will be performed in conjunction with radical prostatectomy, which is an operative code(s) describing the major surgical procedure.

1. Additional Issues Raised by Comments

We received a number of comments on additional specific DRG assignment issues that were not raised in the proposed rule. We are not responding to them individually here because they were not raised in the proposed rule. We will be considering each issue raised for consideration in the FY 2004 DRG reclassifications. We also note that we previously described a process for submission of non-MedPAR data for consideration in evaluating the DRG assignment issue (64 FR 41499).

C. Recalibration of DRG Weights

We are using the same basic methodology for the FY 2003 recalibration as we did for FY 2002 (August 1, 2001 final rule (66 FR 39828)). That is, we recalibrate the weights based on charge data for Medicare discharges. For the proposed rule, we used the most current charge information available, the FY 2001 MedPAR file. (For the FY 2002 recalibration, we used the FY 2000 MedPAR file.) The MedPAR file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills.

The final recalibrated DRG relative weights are constructed from the FY 2001 MedPAR data, which include discharges occurring between October 1, 2000 and September 30, 2001, based on bills received by CMS through March 31, 2002, from all hospitals subject to the acute care hospital inpatient prospective payment system and short-term acute care hospitals in waiver

States. The FY 2001 MedPAR file includes data for approximately 11,483,663 Medicare discharges. The data include hospitals that subsequently became CAHs, although no data are included for hospitals after the point they are certified as CAHs.

The methodology used to calculate the DRG relative weights from the FY 2001 MedPAR file is as follows:

- To the extent possible, all the claims were regrouped using the DRG classification revisions discussed in section II.B. of this preamble.

- Charges were standardized to remove the effects of differences in area wage levels, indirect medical education and disproportionate share payments, and, for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment.

- The average standardized charge per DRG was calculated by summing the standardized charges for all cases in the DRG and dividing that amount by the number of cases classified in the DRG. A transfer case is counted as a fraction of a case based on the ratio of its transfer payment under the per diem payment methodology to the full DRG payment for nontransfer cases. That is, transfer cases paid under the transfer methodology equal to half of what the case would receive as a nontransfer would be counted as 0.5 of a total case.

- We then eliminated statistical outliers, using the same criteria used in computing the current weights. That is, all cases that are outside of 3.0 standard deviations from the mean of the log distribution of both the charges per case and the charges per day for each DRG are eliminated.

- The average charge for each DRG was then recomputed (excluding the statistical outliers) and divided by the national average standardized charge per case to determine the relative weight. (See section II.B.14.f. of this preamble for a discussion of the special adjustment used in calculating the FY 2003 DRG relative weights for DRGs 526 and 527.)

- We established the relative weight for heart and heart-lung, liver, and lung transplants (DRGs 103, 480, and 495) in a manner consistent with the methodology for all other DRGs except that the transplant cases that were used to establish the weights were limited to those Medicare-approved heart, heart-lung, liver, and lung transplant centers that have cases in the FY 1999 MedPAR file. (Medicare coverage for heart, heart-lung, liver, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)

- Acquisition costs for kidney, heart, heart-lung, liver, lung, and pancreas

transplants continue to be paid on a reasonable cost basis. Unlike other excluded costs, the acquisition costs are concentrated in specific DRGs: DRG 302 (Kidney Transplant); DRG 103 (Heart Transplant); DRG 480 (Liver Transplant); DRG 495 (Lung Transplant); and DRGs 512 (Simultaneous Pancreas/Kidney Transplant) and 513 (Pancreas Transplant). Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to make an adjustment to exclude them from the relative weights for these DRGs. Therefore, we subtracted the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average charge for the DRG and before eliminating statistical outliers.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We used that same case threshold in recalibrating the DRG weights for FY 2003. Using the FY 2001 MedPAR data set, there are 41 DRGs that contain fewer than 10 cases. We computed the weights for these 41 low-volume DRGs by adjusting the FY 2002 weights of these DRGs by the percentage change in the average weight of the cases in the other DRGs.

The new weights are normalized by an adjustment factor (1.43889) so that the average case weight after recalibration is equal to the average case weight before recalibration. This adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the prospective payment system.

We did not receive any comments on DRG recalibration.

Section 1886(d)(4)(C)(iii) of the Act requires that, beginning with FY 1991, reclassification and recalibration changes be made in a manner that assures that the aggregate payments are neither greater than nor less than the aggregate payments that would have been made without the changes. Although normalization is intended to achieve this effect, equating the average case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case weight. Therefore, as we have done in past years and as discussed in section II.A.4.a. of the Addendum to this final rule, we make a budget neutrality adjustment to ensure

that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

D. Add-On Payments for New Services and Technologies

1. Background

Section 533(b) of Public Law 106-554 amended section 1886(d)(5) of the Act to add subparagraphs (K) and (L) to establish a process of identifying and ensuring adequate payment for new medical services and technologies under Medicare. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges * * * is inadequate." Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered "new" if it meets criteria established by the Secretary (after notice and opportunity for public comment).

In the September 7, 2001 final rule (66 FR 46902), we established that a new technology would be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (§ 412.87(b)(1)).

We also established that new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system to receive special payment treatment (§ 412.87(b)(3)). To assess whether technologies would be inadequately paid under the DRGs, we established this threshold at one standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned (or the case-weighted average of all relevant DRGs, if the new technology occurs in many different DRGs) (§ 412.87(b)(3)).

Table 10 in the Addendum of this final rule lists the qualifying criteria by DRG based on the discharge data that we are using to calculate the FY 2003 DRG weights. These thresholds will be used to evaluate applicants for new technology add-on payments during FY 2004 (beginning October 1, 2003). Similar to the timetable for applying for new technology add-on payments during FY 2003, we are requiring applicants for FY 2004 to submit a significant sample of the data no later than early October 2002. The complete request also must include a full

description of the clinical applications of the technology and the results of any clinical evaluations demonstrating that the new technology represents a substantial clinical improvement. Subsequently, we are requiring that a complete database be submitted no later than mid-December 2002.

Applications for consideration under this provision for FY 2004 should be sent to the following address: Centers for Medicare & Medicaid Services, c/o Inpatient New Technology Applications, Mail Stop C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244.

In addition to the clinical and cost criteria, we established that, in order to qualify for the special payment treatment, a specific technology must be "new" under the requirements of § 412.87(b)(2) of our regulations. The statutory provision contemplated the special payment treatment for new technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration (no less than 2 years and no more than 3 years). There is a lag of 2 to 3 years from the point a new technology is first introduced on the market and when data reflecting the use of the technology are used to calculate the DRG weights. For example, data from discharges occurring during FY 2001 are used to calculate the FY 2003 DRG weights in this final rule.

Technology may be considered "new" for purposes of this provision within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the technology. After CMS has recalibrated the DRGs to reflect the costs of an otherwise new technology, the special add-on payment for new technology will cease (§ 412.87(b)(2)). For example, an approved new technology that received Food and Drug Administration (FDA) approval in October 2001 would be eligible to receive add-on payments as a new technology until FY 2004 (discharges occurring before October 1, 2003), when data reflecting the costs of the technology would be used to recalibrate the DRG weights. Because the FY 2004 DRG weights will be calculated using FY 2002 MedPAR data, the costs of such a new technology would be reflected in the FY 2004 DRG weights.

In the September 7, 2001 final rule, we established that Medicare would provide higher payments for cases with higher costs involving identified new technologies, while preserving some of the incentives under the average-based payment system. The payment mechanism is based on the cost to

hospitals for the new technology. Under § 412.88, Medicare would pay a marginal cost factor of 50 percent for the costs of the new technology in excess of the full DRG payment. If the actual costs of a new technology case exceed the DRG payment by more than the estimated costs of the new technology, Medicare payment would be limited to the DRG payment plus 50 percent of the estimated costs of the new technology.

The report language accompanying section 533 of Public Law 106-554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rept. No. 106-1033, 106th Cong., 2d Sess. at 897 (2000)). Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual DRG classifications and relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Therefore, we account for projected payments under the new technology provision during the upcoming fiscal year at the same time we estimate the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision would then be included in the budget neutrality factor, which is applied to the standardized amounts and the hospital-specific amounts.

Because any additional payments directed toward new technology under this provision must be offset to ensure budget neutrality, it is important to consider carefully the extent of this provision and ensure that only technologies representing substantial advances are recognized for additional payments. In that regard, we indicated that we will discuss in the annual proposed and final rules those technologies that were considered under this provision; our determination as to whether a particular new technology meets our criteria for a new technology; whether it is determined further that cases involving the new technology would be inadequately paid under the existing DRG payment; and any assumptions that went into the budget neutrality calculations related to additional payments for that new technology, including the expected number, distribution, and costs of these cases.

To balance appropriately Congress' intent to increase Medicare's payments for eligible new technologies with concern that the total size of those payments not result in significantly reduced payments for other cases, we set a target limit for estimated special payments for new technology under the provisions of section 533(b) of Public

Law 106-554 at 1.0 percent of estimated total operating prospective payments.

If the target limit is exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments do not exceed the limit. Using this approach, all cases involving approved new technologies that would otherwise receive additional payments would still receive special payments, albeit at a reduced amount. Although the marginal payment rate for individual technologies would be reduced, this would be offset by large overall payments to hospitals for new technologies under this provision.

Comment: Numerous commenters expressed concern that the method by which payments are made—in a budget neutral manner—reduces the amount of DRG payments for other cases. The commenters noted that shifting money around within the prospective payment system leaves hospitals without the additional money they need to ensure beneficiaries have access to the newest medical tests and treatments. Many of the commenters believed that reducing payments for other services in order to increase payments for new technology is inappropriate, as the costs associated with all other inpatient procedures are not declining. The commenters noted that they will continue to urge Congress to adopt an appropriate adjustment to hospital payments without redistributing payments from elsewhere in the system.

Some commenters also wrote that the new technologies listed in the proposed rule are worthy of additional funding, but, since budget neutrality would reduce payments for all other inpatient procedures, even though costs for these procedures are not declining, the applications should not be approved. However, if the applications are approved, the commenters stressed the need to maintain the requirement that no more than 1 percent of total acute inpatient prospective payments may be used for new technology payments. Furthermore, if actual total add-on payments were less than estimated in calculating the budget neutrality adjustment, the commenters argued that unspent funds should be restored to the standardized amount.

Response: As stated above, the Congressional Report language accompanying section 533 of Public Law 106-554 clearly indicated Congress' intent that this provision is to be implemented in a budget neutral manner. Therefore, the commenters are correct that Congress is the appropriate body to consider concerns about the budget neutrality of this provision. We

also agree with the commenters about the need to limit the total payments made under this provision. In the September 7, 2001 final rule, we established a target limit of 1 percent of total acute inpatient prospective payment system payments for new technology. This target is intended to limit the redistributive impact of these higher payments for new technology relative to payments for other services.

Although our estimates are influenced by past experience, it has been our longstanding practice not to adjust our budget neutrality calculations retroactively on the basis of actual payments. We note that hospitals may either benefit or lose in any given year, depending on whether we underestimate or overestimate the budget neutrality factor. We would note that, in years when hospitals benefited from an underestimate of the budget neutrality factor, we did not recoup any payments resulting from the underestimate.

Comment: Some commenters criticized our implementation of the add-on payment provision for new technology. They claimed that the criteria we set make it impossible for technologies to qualify for add-on payments and suggest that many companies did not apply for new technology add-on payments because the threshold and other criteria were set so high. As proof, the commenters pointed to the small number of applications we received for new technology add-on payments for FY 2003, and to the apparent denial of all applicants. The commenters argued that our criteria operate to nullify the effect of the provision and, therefore, go against Congress' intent.

Response: Unlike the commenters, we believe the limited number of applications lends support to the appropriateness of the criteria. It was our intention to implement this provision without fundamentally disrupting the prospective payment system. A substantial number of cases receiving extra cost-based payments, (or substantial disaggregation of the DRGs into smaller units of payment) would undermine the efficiency incentives of the DRG payment system. This system, is founded on the theory that, by paying for patients with similar clinical characteristics based on the average resources needed to treat those patients, the system creates an incentive for physicians and hospitals to evaluate the most appropriate treatment approach for an individual patient, knowing that the payment to the hospital will, on average, reflect the average resources utilized across all patients in the DRG.

Add-on payments for specific new technologies influence the financial incentives faced by the physician and the hospital, and, because these payments are implemented in a budget neutral manner, they impact the average payments for all DRGs.

While we recognize Congress' intent that Medicare beneficiaries have faster access to new technologies that may be introduced more slowly otherwise due to payment concerns, we believe Congress also did not intend to fundamentally disrupt the incentives of the prospective payment system. We will continue to carefully evaluate whether our criteria appropriately balance these two objectives.

Comment: Many commenters repeated objections to policies proposed in the May 4, 2001 proposed rule (66 FR 22646). These comments are listed here.

Several commenters argued that the one standard deviation threshold was too high for most new technologies to qualify. Commenters also wrote that the substantial clinical improvement criterion should be removed, and that the 50-percent pass-through payment does not adequately reimburse hospitals for the cost of new technologies. Many commenters suggested that we use the 80-percent standard that we use for outlier thresholds.

One commenter objected to our requirement of a "significant sample" of "verifiable" external data. This commenter wrote that any economic data required should be reasonably derived from the clinical trials conducted in conjunction with submissions to the FDA. In addition, our data requirements should not be overly burdensome and should recognize the difficulties faced by hospitals, such as compliance with patient confidentiality regulations.

Some commenters suggested that we incorporate new technologies directly into the DRG system and adjust the weights to reflect the increased costs of the item(s) as data become available. They argued that this method would be more consistent with the fundamental structure of the acute care hospital inpatient prospective payment system and would avoid the complexity of coding and billing for new technology cases.

Some commenters suggested that the ICD-9-CM Coding System cannot continue to be expanded to create new codes to identify new technologies in the long term, and the ICD-10-Procedure Coding System (ICD-10-PCS) would be an appropriate long-term solution. One commenter, a national hospital association, referred to ICD-10-PCS as "the system of choice with

appropriate attention given to implementation, education and system related issues." This commenter recommended that the approval process be revised to include a requirement that the applicant must barcode each item for ease of hospital reporting and billing, based on Universal Product Numbers.

Response: We discussed our positions on each of these issues in detail in the September 7, 2001 final rule (66 FR 46905). We appreciate the interest of the many stakeholders in ensuring that Medicare beneficiaries have full access to improvements in medical technology. Our rationales for these policies have not changed since we discussed them in that final rule, and we did not propose changes to these policies in the May 9, 2002 proposed rule. Therefore, readers are referred to the September 7, 2001 final rule for our responses to these comments. However, we will continue to assess each of these policies as we gain more experience with this provision, and would appreciate the commenters' continued input.

Comment: MedPAC agreed with the approach that we have taken in implementing this provision. MedPAC stated that our approach is "a reasonable compromise between the need to provide quick access to important new technologies for Medicare beneficiaries and not spending more than necessary."

Response: We appreciate the supportive comments submitted by MedPAC.

Comment: In conjunction with concern regarding overall payment decreases as a result of the requirement that add-on payments for new technology be budget neutral, several other commenters indicated that they agreed with our proposed denial of all of the new technology applications.

Response: We want to clarify the misunderstanding expressed by some new technology applicants that we proposed to deny all of the applications. In the May 9, 2002 proposed rule, we stated that, for two of the applicants, Xigris™ and the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device, we were withholding a final determination on whether these technologies represented a substantial clinical improvement or met the cost threshold until the final rule. We did propose to deny the other two applicants, Zyvox™ and Renew™ Radio Frequency Spinal Cord Stimulation Therapy.

Comment: One commenter believed that the cost threshold for a new technology to qualify for add-on payments is too high, but also expressed

concern that recent proposed legislation, which would establish that the cost of new technology must exceed the lesser of the current threshold or 50 percent above the standardized amount (about \$2,100), was too low. This commenter urged us to amend our regulations to continue to allow the threshold to vary by DRG (currently, the threshold is based on the DRG's geometric mean charge plus the DRG's standard deviation of charges), but at a lower level than at present.

However, another commenter argued in favor of the alternative lower threshold. This commenter wrote that the current cost threshold was the primary reason that many technology manufacturers determined that submission of an application for an add-on payment would be fruitless.

Response: We agree with the commenter that the alternative threshold proposed in the legislation is too low. Reducing the threshold to such an extent would lead to many more technologies qualifying for add-on payments, which would be contrary to the bundling theory of the DRG system and would be inflationary. Under these lower thresholds, technology sponsors would have a strong incentive to establish prices for otherwise low-cost technologies at marginally higher levels that would meet this minimal threshold. In contrast, market forces prevent otherwise low-cost technologies being priced at a level sufficient to meet our present, higher threshold. Even though the add-on payments are budget neutral, this price inflation would eventually be reflected in the market basket. On the other hand, the current thresholds greatly limit inflationary pressures by targeting technologies that have extraordinarily high costs. However, we will continue to assess the adequacy of our current criteria as we continue to gain experience implementing the provision for add-on payments for new technologies.

Comment: One commenter argued that the evaluation of an application for the substantial improvement criteria should focus on the potential for the new technology to result in a substantial improvement over currently covered therapies. The commenter noted that very few medical devices are approved by the FDA on the basis of clinical trials that directly compare the new technology to other Medicare-covered alternatives. Data demonstrating a clear advantage in clinical outcomes are often not available until several years after FDA approval.

The commenter believed this approach would be beneficial to CMS, noting that the current process suggests

a coverage-type analysis, potentially limiting CMS' ability to undertake any later coverage review after a substantial improvement determination is made. The commenter added that denying a request on the basis that a technology does not represent a substantial improvement could lead local Medicare contractors to restrict coverage based upon such a denial.

Response: We disagree that data needed to evaluate whether new devices are a substantial improvement over current therapies are unavailable until years after the technology is introduced. Our experience evaluating the applications discussed below, as well as under the outpatient prospective payment system pass-through policy, demonstrates that the sponsors of new technologies generally do collect data that can be used to assess whether a new technology is a substantial improvement over previously available technologies. Further, we believe it would be difficult, if not infeasible, to assess objectively the validity of an unsupported claim about potential outcomes. Rather, we believe it is appropriate and reasonable to expect applicants to present verifiable data demonstrating a substantial improvement of any applicant new technology relative to available alternatives.

We also do not believe that denial of an application on the grounds that the new technology is not a substantial improvement over existing technologies would lead to Medicare's contractors denying coverage. The criteria for substantial improvement determinations are quite different from coverage determinations, and we do not believe our contractors are likely to confuse the two.

Comment: One commenter wrote that it would be inappropriate to apply the budget neutrality adjustment to the hospital-specific payments to sole community hospitals (SCHs) and Medicare-dependent hospitals (MDHs). The commenter's argument appears to be based on the presumption that the add-on payments would not be available to hospitals paid using the hospital-specific rates.

Response: The commenter has correctly pointed out that we did not address whether add-on payments would be made to SCHs or MDHs paid on the basis of their hospital-specific amount in accordance with § 412.92(d) and § 412.108(c), respectively. We believe these additional payments for new technologies should be available to SCHs and MDHs paid on the basis of their hospital-specific amounts. These hospitals' payments under the hospital-

specific amount methodology are adjusted by the DRG weight for each discharge. Because the costs of new technology would not be reflected in the base years used to calculate the applicable hospital-specific amounts, it is appropriate to provide for these hospitals to receive the add-on payments under this provision. Therefore, we are amending § 412.88(a)(1) to reflect this oversight.

Because SCHs and MDHs will be eligible to receive add-on payments in addition to their hospital-specific amounts, it is also appropriate to apply the applicable budget neutrality adjustments to the hospital-specific amounts.

Comment: Some commenters requested a payment calculation, showing that the add-on payment is made before the outlier adjustment. The commenters also were confused about the add-on payments in transfer situations. They wanted clarification on whether the transferring hospital would get the full add-on payment or if it would receive a prorated payment, and requested an example.

In addition, one commenter asked whether payments for indirect medical education (IME) or the disproportionate share hospital (DSH) adjustment are included in the "DRG payment amount" that is compared against costs to determine whether an individual case qualifies for the add-on payment. The commenter argued that if the add-on payment amount is calculated before outlier payments, it would logically follow that they would also be calculated before IME and DSH payments.

Response: The commenters are correct that the add-on payment is made prior to calculating whether the case qualifies for outlier payments (see § 412.80(a)(3)). In response to the request for a payment example, consider a new technology estimated to cost \$3,000, in a DRG that pays \$20,000. A hospital submits three claims for cases involving this new technology. After applying the hospital's cost-to-charge ratio, it is determined that the costs of these three cases are \$19,000, \$22,000, and \$25,000. Under the proposed approach, Medicare would pay \$20,000 (the DRG payment, including any IME or DSH payments) for the first claim. For the second claim, Medicare would pay one half of the amount by which the costs of the case exceed the DRG payment, up to the estimated cost of the new technology, or \$21,000 (\$20,000 plus one half of the amount by which costs of the case exceed the standard DRG payment). For the third claim, Medicare would pay \$21,500 (\$20,000 plus one half of the

total estimated costs of the new technology). In the event the hospital had a fourth case with extraordinarily high costs, the fixed-loss outlier threshold would be applied to the total DRG payment plus the add-on payment for new technology (\$21,500), for comparison with the actual costs to determine whether the case would qualify for outlier payments.

With respect to the comment requesting clarification regarding the amount of the add-on payment made to a transferring hospital where the new technology eligible for add-on payments is provided prior to the transfer, the amount of the new technology add-on payment is not adjusted, but is paid up to 50 percent of the full cost of the new technology. This is appropriate because the hospital is likely to incur the full cost of the new technology when it is used. We are amending § 412.88(a)(1) to reflect this clarification.

With respect to whether IME and DSH payments are excluded from the comparison between the full DRG payment for the case and the costs for purposes of computing the add-on payment, § 412.88(a)(1) states that the full DRG payment "includes indirect medical education and disproportionate share." This amount is then compared to the costs of the discharge to compute the amount of the add-on payment § 412.88(a).

Comment: One commenter, representing a national hospital association, recommended against approving new technologies with very limited utilization because these technologies should already be receiving additional funds as outlier cases, and the added administrative burden of including these items negates any benefit. This commenter also suggested that we limit the number of applications that can be approved by setting a minimum of \$30 million in projected payments for each new technology.

This commenter argued that this limitation would reflect the added burden and administrative expense for hospitals associated with each additional new technology item that is approved. The commenter stated that training and operational and behavioral changes in response to specific coding requirements were examples of such additional costs.

Response: We believe the incremental costs to hospitals associated with this provision should be minimal. Specifically, the additional payments are triggered by the presence of an ICD-9-CM code on the bill, information already required to process the claim for normal DRG payment. Accordingly,

there should be little need for training or other operational changes in response to the approval of a new technology for add-on payments.

Comment: Commenters requested further guidance for future applications.

Response: We are developing more detailed instructions for applicants, based on our experience in processing the FY 2003 applications. In the meantime, individuals interested in obtaining more information about the application process should call the Division of Acute Care at (410) 786-4548.

2. Applicants for FY 2003

We received five applications for new technologies to be designated eligible for inpatient add-on payments for new technology. One of these applications was subsequently withdrawn. In the proposed rule, we proposed that two of the applicants, Zyvox™ and Renew™ Radio Frequency Spinal Cord Stimulation Therapy, did not meet our criteria. We withheld a final determination on two other applicants, Xigris™ and the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device, pending further review to determine whether they met the substantial clinical improvement criteria.

Comment: A few commenters noted that, according to the final rule last year (66 FR 46914), we indicated we would propose our determination regarding new technology applications in the proposed rule. The public would then have the opportunity to comment on the proposed determinations. Because the FY 2003 proposed rule did not include specific proposed determinations for two technologies, the commenters argued that we did not give the public and the provider community an appropriate notice and comment period before the decisions take effect on October 1, 2002. These commenters urged us to allow for additional public comments on our final decisions announced in this final rule.

Response: We presented the results of our analysis of the available data in the May 9, 2002 proposed rule, including the budget neutrality implications, to provide an opportunity for those interested to submit specific comments on the applications. In fact, we did receive comments on specific aspects of the applications, as noted below. In addition, we clearly indicated in the proposed rule we were continuing to evaluate Xigris™ and the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device for possible approval in the final rule (67 FR 31428 and 31429). Therefore, we believe

interested parties had sufficient information to evaluate our proposed decisions and to provide informed comments. For these reasons, we are not extending the period for providing public comment on the decisions on applicants announced below.

We also noted in the May 9 proposed rule that, due to the very limited timeframe between enactment of this provision, its implementation through the final rule, and the deadlines to submit applications for consideration for FY 2003, it was necessary to be more flexible this first year in working with the applicants to ensure that they were given every opportunity to demonstrate that their new technology qualified for add-on payments. Insofar as possible, we intend in the future to announce our proposed determinations in the annual proposed rule updating the acute care hospital inpatient prospective payment system.

a. Drotrecogin Alfa (Activated)—Xigris™

Eli Lilly and Company (Lilly) developed drotrecogin alfa (activated), trade name Xigris™, as a new technology and submitted an application to us for consideration under the new technology add-on provision. Xigris™ is used to treat patients with severe sepsis.

According to the application—
"Approximately 750,000 cases of sepsis associated with acute organ dysfunction (severe sepsis) occur annually in the United States. The mortality rates associated with severe sepsis in the United States range from 28 percent to 50 percent and have remained essentially unchanged for several decades. Each year, 215,000 deaths are associated with severe sepsis; deaths after acute myocardial infarction occur at approximately an equal rate."

Xigris™ is a biotechnology product that is a recombinant version of naturally occurring Activated Protein C (APC). APC is needed to ensure the control of inflammation and clotting in the blood vessels. In patients with severe sepsis, Protein C cannot be converted in sufficient quantities to the activated form. It appears that Xigris™ has the ability to bring blood clotting and inflammation back into balance and restore blood flow to the organs.

In support of its application, Lilly submitted data from the Phase III Protein C Worldwide Evaluation in Severe Sepsis (PROWESS) trial. According to Lilly, this was "an international, multicenter, randomized, double-blind, placebo-controlled trial in which 1,690 patients with severe sepsis received either placebo (n = 840) or

drotrecogin alfa (activated) (n = 850).” The results of the trial were published in an article in the March 8, 2001 edition of *The New England Journal of Medicine* (Bernard, G. R., Vincent, J. L., et al., “Efficacy and Safety of Recombinant Human Activated Protein C for Severe Sepsis,” Vol. 344, No. 10, p. 699).

Xigris™ was approved by the FDA in November 2001. In its approval letter, the FDA wrote that this biologic “is indicated for the reduction of mortality in adult patients with severe sepsis (sepsis associated with acute organ dysfunction) who have a high risk of death (for example, as determined by APACHE II [acute physiology and chronic health evaluation]).” In the May 9, 2002, proposed rule, however, we indicated that we were unable to conclude, based on the published data, that Xigris™ represents an advance that substantially improves, relative to technology previously available, treatment for Medicare beneficiaries. Specifically, because the reduction in mortality in the published data was the result of a treatment effect in a relatively small number of patients and mortality was examined for only 28 days after treatment, we indicated that we planned to review unpublished data on all-cause mortality at the time of hospital discharge for all patients enrolled in the study.

Subsequent to the publication of the proposed rule, Lilly submitted additional data in response to our request. The major endpoint of the PROWESS study was a reported reduction in 28-day all-cause mortality of 6.1 percent. At the time the study ended, many of the participants were still hospitalized and whether they would ultimately recover was unknown. We requested data about those hospitalized patients to determine if the reported advantage in mortality from Xigris™ use persisted for all study participants. These data are now available and show an overall decrease in mortality for all patients, including patients over 65 years of age.

Therefore, we have concluded that, when used in accordance with the following FDA-listed indications and contraindications, Xigris™ meets the substantial improvement criteria for additional payment for new medical services and technologies under § 412.87(b)(1):

- Active internal bleeding;
- Recent (within 3 months) hemorrhagic stroke;
- Recent (within 2 months) intracranial or intraspinal surgery or severe head trauma;

- Trauma with an increased risk of like-threatening bleeding;
- Presence of an epidural catheter;
- Intracranial neoplasm or mass lesion or evidence of cerebral herniation.

Detailed bills were available for 604 of 705 patients in the United States in the PROWESS clinical trial (303 placebo patients and 301 treatment patients). In all, 83 hospitals submitted detailed bills. Of the 604 cases with detailed billing data, 274 were patients age 65 or older. The average total charge for these 274 cases, including the average standardized charge for the biological, was \$86,184 (adjusted for inflation using the applicable hospital market baskets, as patients were enrolled in the trial from July 1998 through June 2000). The inflated average standardized charge of the biological only for these cases was \$15,562.

Lilly also submitted detailed ICD-9-CM diagnosis and procedure codes for a subset of 157 of the 604 U.S. patients with billing data from the PROWESS trial. These data were not requested as part of the trial, but were sent in separately. Of these 157 patients, 82 were over 65 years of age. These 82 patients grouped into 23 DRGs. Approximately 75 percent of these 82 cases were in 5 DRGs: 29 percent were in DRG 475 (Respiratory System Diagnosis with Ventilator Support); 17 percent were in DRG 483 (Tracheostomy Except for Face, Mouth, and Neck Diagnoses); 15 percent were in DRG 416 (Septicemia Age>17); 7 percent were in DRG 415 (OR Procedure for Infectious and Parasitic Diseases); and 5 percent were in DRG 148 (Major Small and Large Bowel Procedures With CC).

Using the methodology described in the September 7, 2001 final rule (66 FR 46918), we calculated a case-weighted threshold based on the distribution of these 82 cases across 23 DRGs. In order to qualify for new technology payments based on these DRGs, the threshold would be \$82,882 (compared to the average standardized charge of \$86,184 noted above).

In the September 7, 2001 final rule, we stated that the data submitted must be of a sufficient sample size to demonstrate a significant likelihood that the sample mean approximates the true mean across all cases likely to receive the new technology. Using a standard statistical methodology for determining the needed (random) sample size based on the standard deviations of the DRGs identified in the trial as likely to include cases receiving Xigris™, we have determined that a random sample of 274 cases can be reasonably expected to produce an estimate within \$3,500 of

the true mean.² Of course, the data submitted do not represent a random sample of all cases in these DRGs across all hospitals.

The 274 case sample was for all U.S. patients over age 65 included in the PROWESS trial. In the September 7, 2001 final rule, we indicated our preference for using Medicare cases identifiable in our MedPAR database, although data from a trial without matching MedPAR data could be considered. We also indicated our intention to independently verify the data submitted.

We noted in the May 9, 2002 proposed rule (67 FR 31429) that, due to the passage of Public Law 106-554 in December 2000, and the publication of the final rule in September 2001, it was understandable that the data requirements that were included in the final rule in order to ensure that we would receive the information necessary to analyze applicants for new technology add-on payments were not accommodated in the design of the PROWESS trial. Therefore, in this case, it was necessary for CMS to work with Lilly to verify independently the data in order to determine whether Xigris™ represents a substantial clinical improvement.

After publication of the proposed rule, we analyzed our MedPAR data to develop a cohort group of patients in order to assess the validity of the charges reported for the patients in the PROWESS trial. Using the same methodology as Lilly, we were able to identify a cohort group of cases in the MedPAR data with similar criteria as the patients who were screened for the PROWESS trial and were discharged from the hospitals included in the trial. We calculated that the average total charges for these cases closely approximated the total charges that Lilly sent with its analysis. Based on this analysis, we have determined that the average standardized charges of \$86,184 described above exceeds the cost threshold criteria of \$82,882 for the DRGs involved. Therefore, we are approving Xigris™ for add-on payments under § 412.88, to be effective for FY 2003 and FY 2004.

Cases where Xigris™ is administered will be identified by use of the new ICD-9-CM procedure code 00.11 (Infusion of drotrecogin alfa (activated)). According to Lilly, “(t)he net wholesale

² The formula is $n = 4\sigma^2/B^2$, where σ is the standard deviation of the population, and B is the bound on the error of the estimate (the range within which the sample means can reliably predict the population mean). See *Statistics for Management and Economics*, Fifth Edition, by Mendenhall, W., Reinmuth, J., Beaver, R., and Duhan, D.

price for drotrecogin alfa (activated) is \$210 for a 5-milligram vial and \$840 for a 20-milligram vial. The average cost for a one-time 96-hour course of therapy for an average adult patient is \$6,800 (24µg/kg/hr for 96 hours for a 70kg person).” Therefore, cases involving the administration of Xigris™ as identified by the presence of code 00.11 are eligible for additional payments of up to \$3,400 (50 percent of the average cost of the drug).

For purposes of budget neutrality, we have estimated the additional payments that would be made under this provision during FY 2003. Lilly had estimated that, initially, 25,000 Medicare patients would receive Xigris™. However, Lilly’s estimate does not fully reflect severe sepsis patients who may not have multiple organ failure, but for whom Xigris™ is indicated nonetheless due to APACHE II scores in the third and fourth quartiles. Therefore, for purposes of our budget neutrality estimates, we are projecting 50,000 Medicare patients will receive Xigris™ during FY 2003. We believe this projection reflects modest growth in FY 2003 from \$35 million in sales reported by Lilly through February 2002 (since the drug was approved in November 2001). (At \$6,800 per patient, \$35 million in sales equates to just over 5,000 cases for the first 4 months since FDA approval.) We note that some analysts project sales of Xigris™ as high as approximately 100,000 cases annually. We believe our estimate reflects the potential for growth beyond the current usage since FDA approval in November 2001, and for the use of Xigris™ in treating patients without multiple organ failure for whom the drug is indicated but who were not included in Lilly’s estimate.

If the maximum \$3,400 add-on payment is made for all 50,000 of these patients, the total amount that would be paid for these cases would be an additional \$170 million. However, comparing the total standardized charges for the 274 patients age 65 or older, we calculated that 56 percent had average standardized charges below the weighted average standardized charges for the 23 DRGs into which these cases were categorized. Therefore, assuming the costs for these cases would be below the payment received, these 56 percent of cases would not receive any additional payment. Therefore, for purposes of budget neutrality, we estimate the total payments likely to be made under this provision during FY 2003 for cases involving the administration of Xigris™ would be \$74.8 million (44 percent of \$170 million).

Comment: Numerous commenters recommended that we approve Xigris™. Many of the commenters described Xigris™ as a major advance in the treatment of patients with severe sepsis. However, some commenters indicated that its use has substantially increased the costs of caring for these patients. One commenter reported rationing of this drug at some institutions due to cost considerations. Another commenter submitted an article from a pharmaceutical newsletter recommending the “best method for patient selection is to use the criteria for enrollment in the PROWESS trial.”

Response: We are pleased to approve Xigris™ for add-on payments under this provision. As described above, we believe this drug represents a substantial improvement over currently available therapies for the treatment of severe sepsis in patients who have a high risk of death. We note that our finding that Xigris™ represents a substantial clinical improvement is limited to the indications and contraindications listed in the approved FDA labeling guidelines.

Comment: Some commenters, including the applicant, objected to CMS’ request for additional data and endpoints beyond those requested by the FDA for its approval of Xigris™. The commenters argued that the FDA has the regulatory responsibility to monitor safety and efficacy of drugs and medical devices and provides rigorous review and oversight to the approval of drugs. They further contended that the placement of drugs under FDA “priority review” process for approval should be given weight when determining whether a drug meets the CMS “substantial improvement” criteria.

According to the commenters, by asking manufacturers for additional data to determine if an applicant meets our substantial clinical improvement criteria, CMS has inappropriately substituted its judgment for that of the FDA. The commenters suggested that we implement policies to ensure that these “improprieties” will not be repeated. One commenter argued that, if we plan to ask for unpublished data from future sponsors, we should amend our rulemaking to specify the conditions under which unpublished data may be required.

Response: Although we are affiliated with the FDA and we do not question the FDA’s regulatory responsibility for decisions to approve drugs, we are not using FDA guidelines to determine what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria do not depend on the standard of safety and

efficacy that the FDA sets for general use, but on a demonstration of substantial clinical improvement in the Medicare population (particularly patients over age 65).

To clarify this distinction, we offer the following example. The FDA approves a drug for general use to control the effects of seasonal allergies. This drug works well and has minimal side effects, but it makes some people feel nauseous if they take it without food. Two years later, another company creates a new allergy medicine that does not cause nausea. This drug also gets approval from the FDA. This does not necessarily mean that the new drug represents a substantial clinical improvement over the existing drug. The new drug may be better for some patients to take, but it is only an equivalent treatment, or another option, to the first drug. Therefore, the new drug would not meet the CMS substantial clinical improvement criteria.

We also disagree with the suggestion that the FDA priority review process should be the standard by which CMS should approve new technologies for add-on pass-through payments. We do not want to accept a priority review determination by the FDA as a *de facto* substantial improvement determination by us because: (1) The FDA decision is made prior to reviewing all the clinical data about the product (the decision to review the marketing application as a priority review is made at the beginning of the review process); (2) if the FDA changes its criteria for priority review, it would change the criteria for substantial improvement; (3) the current criteria used by the FDA for priority review are not the same across product types; (4) the criteria for priority review are not exactly the same as CMS substantial improvement in all instances; and (5) it would mean that the FDA would be making a *de facto* reasonable and necessary determination, since a product that offers a substantial improvement is certainly reasonable and necessary.

With respect to the comments regarding the request for submission of unpublished data, we note that the September 7, 2001 final rule indicated that we would require applicants to submit evidence that the technology does provide a substantial clinical improvement over existing technologies (66 FR 46914). Therefore, we disagree with the commenter that it is necessary to amend our regulatory process in this regard.

Comment: The applicant commenter made several additional points in addition to the previous comment. The

applicant objected to the suggestion in the proposed rule that payment would likely be limited to patients meeting the FDA labeling guidelines. The applicant also objected to the statement in the proposed rule that the charge data submitted did not represent a random sample. The applicant reiterated its estimate that 25,000 Medicare beneficiaries would receive Xigris™ in FY 2003.

Response: We are approving Xigris™ for add-on payments on the basis that it represents a substantial clinical improvement over other treatments for patients consistent with the FDA-listed indications. We do not have an administrable mechanism to identify patients who may receive this drug without having the FDA-listed indications. We will review potential options to enable us to more precisely make such distinctions in the future. We reserve the right to reexamine the issue of limiting the types of patients for which add-on payments are made for FY 2004.

In determining whether a new technology is eligible for add-on payments, we compare the average standardized charges of cases involving the applicant technology to the weighted threshold of the relevant DRGs, which reflects the charges of all cases in those DRGs that are discharged from all hospitals (weighted by the number of cases in each DRG). Thus, our statement that the data submitted did not represent a random sample was made in the context of measuring whether the average standardized charge of the PROWESS trial data was statistically significantly higher than the threshold. In order for such a significance test to be truly valid, the trial cases would have to have been drawn randomly from all cases and all hospitals with cases in the relevant DRGs. Clearly, the PROWESS trial was not designed in this manner, nor would we expect it to be. Thus, we were attempting to approximate a standard using a methodology that requires certain assumptions that were not met by the data at hand, and we were merely acknowledging it was only an approximation.

As stated above, we believe the applicant's estimate of 25,000 Medicare patients receiving Xigris™ during FY 2003 does not reflect cases without multiple organ failures but with APACHE II scores in the third and fourth quartiles.

Comment: Some commenters noted that ICD-9-CM codes do not distinguish between dosage amounts for drugs. They recommended (at least until ICD-10-PCS becomes available) relying on

ICD-9-CM for identifying new procedures such as a new pancreas implant or a minimally invasive hip replacement; and incorporating the HCPCS Level II codes. (HCPCS stands for Health Care Financing Administration [recently renamed the Centers for Medicare & Medicaid Services] Common Procedure Coding System) for new drugs or supplies.

One commenter indicated that ICD-9-CM codes appear to be sufficient at this time, but, as new technologies proliferate, they will become overwhelming. However, the commenter did request guidance from us about using "nontraditional" ICD-9-CM codes, as well as information about reporting these codes in instances where more than six procedure codes (the maximum spaces provided on the bill) are involved.

Response: We appreciate the insight provided by this commenter regarding future coding options and will take it into consideration as we look to future refinements to this policy. However, for the reasons addressed at length in the September 7, 2001 final rule, we are using the ICD-9-CM codes at this time to identify cases eligible for the new technology add-on (66 FR 46909-10). However, because of limited space available for new ICD-9-CM codes, we are unable at this time to differentiate the volume of drugs that are administered. Therefore, as described above, we will pay on the basis of an average dose per patient.

As stated above, add-on payments for Xigris™ will be calculated for cases identified by use of the ICD-9-CM code 00.11 (when other conditions are met). In relation to guidance on the use of this code, we believe the documentation requirements are straightforward: consistent with the definition of the code, the medical record must indicate infusion of drotrecogin alfa (activated). With respect to situations where more than six procedure codes may be involved, hospitals should follow normal coding guidelines for selecting which codes to include.

b. Bone Morphogenetic Proteins (BMPs) for Spinal Fusions

BMPs have been isolated and shown to have the capacity to induce new bone formation. Using recombinant techniques, some BMPs (referred to as rhBMPs) can be produced in large quantities. This has cleared the way for their potential use in a variety of clinical applications such as in delayed unions and nonunions of fractured bones and spinal fusions. One such product, rhBMP-2, is developed for use

instead of a bone graft with spinal fusions.

An application was submitted by Medtronic Sofamor Danek for the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device for approval as a new technology eligible for add-on payments. The product is applied through use of an absorbable collagen sponge and an interbody fusion device, which is then implanted at the fusion site. The patient undergoes a spinal fusion, and the product is placed at the fusion site to promote bone growth. This is done in place of the more traditional use of autogenous iliac crest bone graft.

In 1997, in a pilot study conducted under a FDA approved device exemption, 14 patients were enrolled at 4 investigational sites. Eleven patients received rhBMP-2, with 3 control patients. Radiographs and computed tomography scans at 6, 12, and 24 months after surgery showed that all 11 patients who received rhBMP-2 had solid fusions, whereas only 2 of the 3 patients who received autogenous bone graft had solid fusions. Scores from the Oswestry Low Back Pain Disability Questionnaire showed that 6 of 11 patients treated with rhBMP-2 had a successful outcome at 3 months after surgery, compared with 0 of 3 control patients. After 6 months, the results had changed to 7 of 11 rhBMP-2 patients and 2 control patients with successful treatments; and at 12 months, 10 rhBMP-2 patients and 2 control patients were judged successful. The results were unchanged at 24 months. The trial results were presented in an article in the February 1, 2000 edition of SPINE (Bone, S., Zdeblick, T., et al., "The Use of rhBMP-2 in Interbody Fusion Cages—Definitive Evidence of Osteoinduction in Humans: A Preliminary Report"), Vol. 25, No. 3, p. 376.

The above study was then expanded to involve 281 patients at 16 sites, with 143 patients in the rhBMP-2 group and 138 patients in the autogenous iliac crest bone graft group. In the rhBMP-2 group, 76.9 percent of the patients showed an improvement of at least 15 points in their disability scores at 12 months postoperatively. This compared favorably to 75 percent of patients in the control group. At 6 months following surgery, 97 percent of patients in the rhBMP-2 group showed evidence of interbody fusion, as compared to 95.8 percent in the control group. At 12 months, 96.9 percent of patients in the rhBMP-2 group were fused as compared to 92.5 percent in the control group. At this time, the results of this study are unpublished.

Cost data were submitted for 88 patients participating in the follow-up study described above. This trial was a single-level, anterior lumbar interbody fusion clinical study. Of the 88 bills with cost data, the applicant calculated an average standardized charge for these single-level fusion cases of \$33,757. According to the applicant, "it is anticipated that a large number, if not the majority, of cases using BMP technology will, in practice, be multi-level fusions." The applicant reported the estimated hospital charges (based on general charging practices) to be \$17,780 for each level. In order to account for the use of this technology in multilevel spinal fusions, the applicant assumed 47 percent of spinal fusions were multilevel (based on analysis of Medicare spinal fusion cases). Increasing the average standardized charge for the cases in the trial by \$17,780, the applicant calculated a weighted average standardized charge (53 percent single-level and 47 percent multilevel) of \$45,556.

Of these 88 cases, 11 were assigned to DRG 497 (Spinal Fusion Except Cervical With CC) and 77 were assigned to DRG 498 (Spinal Fusion Except Cervical Without CC). In order to qualify for new technology payments based on these DRGs, the threshold would be \$37,815.

At the time of the proposed rule, this technology was not approved for general use by the FDA. Therefore, we indicated that if the FDA approved the product for general use prior to our issuance of the final rule, we would issue a determination whether this technology represents a substantial clinical improvement under the criteria outlined in the September 7, 2001 final rule.

On July 2, 2002, the FDA approved this technology. The approval was for spinal fusion procedures in skeletally mature patients with degenerative disc disease at one level from L4-S1. Therefore, based on the FDA's approval, multilevel usages of this technology would be off-label. As noted above, this technology would meet the cost threshold only if the added costs of multilevel fusions are taken into account. Because the FDA has not approved this technology for multilevel fusions, and the applicant has not submitted data to demonstrate this technology is a substantial clinical improvement for multilevel fusions (as described above, the clinical trial upon which the application was based was a single-level fusion trial), we cannot issue a substantial clinical improvement determination for multilevel fusions. Therefore, because the average charges for this new technology, when used for single-level spinal fusions, does not

exceed the threshold of \$37,815 noted above, we are denying this application for add-on payments during FY 2003. Because the new technology did not qualify on the basis of charges above the thresholds, we did not make a substantial improvement determination.

Comment: A few commenters were very supportive of approving Medtronic Sofamor Danek's InFUSE™ Bone Graft technology. These commenters note that this rhBMP-2 technology is a substantial clinical improvement as it obviates the need for a second surgical procedure to harvest autogenous iliac crest bone. The commenters noted that this substantial improvement focuses mostly on relief of pain in patients because many patients who undergo bone harvesting have pain at the donor site up to 10 years after the surgery.

Several other commenters, however, recommend that we not approve this application for add-on payments. These commenters stated that "the clinical trial results solidly counter the claim of significant improvement." Commenters also objected to the data that the manufacturer provided, stating that in order for the threshold to be met, the manufacturer provided estimates for procedures that would involve multilevel fusions. At the time of the proposed rule, the FDA had not approved the treatment, and commenters noted that the FDA could not approve the treatment for multilevel surgeries because it had been given no clinical evidence for these procedures. The commenters pointed out that FDA's approval (which came on July 2, 2002) could (and does) only indicate approval for use of the product for single-level fusions. Therefore, the commenters strongly opposed the approval of the BMP applicant because it does not meet our financial threshold. The commenters also were concerned that, if approved for new technology payments, the technology may be used inappropriately off label and for indications that have not been approved by the FDA.

Response: We stated in the September 7, 2001 final rule that we believe the technologies approved for add-on payments should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology (66 FR 46913). Further, we stated that we believe it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives

created to quickly adopt new technology.

As noted above, we are denying this application for add-on payments during FY 2003 because it does not meet our cost threshold when used for single-level spinal fusions, and there is no available evidence upon which to determine whether it represents a substantial improvement for multilevel uses.

c. Zyvox™

Zyvox™ is the first antibiotic in the oxazolidinone class and is widely used by hospitals in the United States and other countries against the medically significant gram-positive bacteria, including those that are resistant to other therapies. Gram-positive bacterial infections have become increasingly prevalent in recent years, most commonly implicated in infections in the lower respiratory tract, skin and soft tissue, bone and bloodstream, and in meningitis. Significant morbidity and mortality trends are associated with such pathogens. Epinomics Research, Inc., submitted the application on behalf of Pharmacia Corporation (Pharmacia), which markets the drug.

The FDA approved Zyvox™ on April 18, 2000, for the treatment of serious infections caused by antibiotic-resistant bacteria. The applicant contends that this qualifies Zyvox™ for approval within the 2-year to 3-year period referenced at § 412.87(b)(2). Furthermore, the applicant notes that the approval of the new ICD-9-CM code 00.14 (Injection or infusion of oxazolidinone class of antibiotics) effective October 1, 2002, will permit a more precise identification of these cases. However, as noted previously, technology will no longer be considered new after the costs of the technology are reflected in the DRG weights. Because the costs of Zyvox™ are currently reflected in the DRG weights, Zyvox™ does not meet our criterion that a medical service or technology be "new". The FY 2001 MedPAR data used to calculate the proposed DRG weights for FY 2003 include cases where Zyvox™ was administered. The application itself noted that the use of Zyvox™ is widespread. Therefore, even though the existing code, 99.21 (Injection of antibiotic) is a general code used for the administration of various antibiotics including Zyvox™, and does not separately identify the administration of Zyvox™ as will be possible with the new code 00.14, the charges associated with these cases are reflected in the proposed FY 2003 DRG weights.

As stated above, we note that the applicant itself points out that Zyvox™

is widely used currently by hospitals. In its 4th quarter 2001 earnings report, Pharmacia reports total sales in the United States of \$97 million, which is an increase of 105 percent over the previous year. This would indicate expanding access to the drug.

We would point out that, in response to a comment that technologies should qualify as “new” beginning with the assignment of an appropriate tracking code, we clarified in the September 7, 2001 final rule that we would not consider technologies that have been on the market for more than 2 or 3 years to be “new” on the basis that a more precise ICD–9–CM procedure code has been created (66 FR 46914). However, although such technologies would not qualify for add-on payments under this provision, we did indicate that we would evaluate whether the existing DRG assignments of the technology are appropriate.

For example, currently the administration of Zyvox™ does not affect the DRG to which a case is assigned. In its application for add-on payments, Epinomics provided CMS data that included clinical trials as well as data from a sample that spanned MedPAR files from FY 2000 through FY 2002. For its sample study, Epinomics obtained patient records from 70 hospitals that used Zyvox™ treatment on 832 Medicare patients. The cases were distributed across 151 DRGs. Epinomics calculated that the mean standardized charge for these 485 cases was \$74,174. The case-weighted mean standardized charge for all cases in these DRGs would be \$33,740 (based on the distribution of Zyvox™ cases across the 151 DRGs).

The unit price for the drug varies from approximately \$30 for a 100 milliliter bag (200 milligram linezolid) to approximately \$1,350 for 600 milligram tablets (unit doses of 30 tablets). Nevertheless, it appears the high average charges associated with patients receiving the drug are not directly attributable to the administration of Zyvox™. Therefore, in the May 9, 2002 proposed rule, we did not propose any changes to the DRG assignment of these cases. We indicated that to the extent these cases are more expensive due to the severity of illness of the patients being treated, the current outlier policy will offset any extraordinarily high costs incurred.

Comment: Several commenters, including the applicant, strongly objected to our denial of Zyvox™ for new technology payments. They criticized our decision not to approve it on the grounds that payments for this expensive drug are already incorporated

into the DRG recalibration for FY 2003. The commenters argued that, based on the recent assignment of an ICD–9–CM code, the drug still qualifies for add-on payments under the Congressional intent of the law.

The commenters referenced the language of section 1886(d)(5)(K)(ii)(II) of the Act in support of their claim that this technology qualifies as new. They believed the 2-year to 3-year period “beginning on the date on which an inpatient hospital code is issued with respect to the service or technology” applicable to Zyvox™ should begin October 1, 2002, when new code 00.14 becomes effective. They argued that this new code will allow data to be accumulated to track the costs of these cases.

Response: Again, we do not believe it would be appropriate to consider technologies that have been on the market for 2 or 3 years for approval under this provision on the basis that a new, more precise, procedure code is subsequently issued. Allowing technologies that have already been in use to attain higher payments as a result of the assignment of a new, more specific ICD–9–CM code would open the door for the sponsors of any medical device or technology to consider whether they might qualify their product for add-on payments by requesting and receiving a new code from the ICD–9–CM Coordination and Maintenance Committee. We do not believe it was Congress’ intent that this provision should be interpreted that way.

Therefore, it is necessary to establish a point after which previously existing technologies are not eligible to qualify for add-on payments under this new provision. We believe it is reasonable to establish the cutoff point such that those technologies with data available in the FY 2001 MedPAR to be included in the calculation of the FY 2003 DRG weights will not be eligible for new technology payments. We note that this process of incorporating new technologies into existing DRGs, where they eventually affect the weights depending on their utilization, was how all new technologies have been introduced since 1984. While we recognize Congress’ intent to revise this process to expedite the introduction of new technologies, there was no indication in the legislation that the new policy was to apply to technologies whose costs were already reflected in the DRG weights.

Comment: The applicant criticized CMS for delaying the implementation of the provision. The commenter noted that the provision was to be implemented, “[n]ot later than October

1, 2001” and stated that CMS failed to implement the law by October 1, 2001. They argued that, by delaying the implementation, CMS effectively prevented Zyvox™ from ever meeting the “new” criteria, even though the drug got approval only 8 months before the provision was passed.

Response: We disagree that we delayed implementation of this provision. In the September 7, 2001 final rule, we stated that, although we did not approve any new technologies for add-on payments effective October 1, 2001, we did carefully evaluate all technologies that were brought to our attention, either as a result of our internal analysis or by the public, including those submitted for consideration during the public comment period on the May 4, 2001 proposed rule. Zyvox™ was not among the technologies submitted for consideration at that time.

Comment: Commenters argued that, although Zyvox™ was available and used during FY 2001, and therefore would be reflected in hospitals’ charges used to set the FY 2003 DRG relative weights, due to the high cost of the drug, it is far from clear that hospitals prescribed the product for the majority of Medicare patients for whom it would be most appropriate. Therefore, the impact of the costs of the drug on the DRG weights is understated.

Response: We cannot assess whether the utilization of Zyvox™ was hampered by Medicare payments during FY 2001. However, we would note that Zyvox™ was treated in the same manner as other new technologies have been over the years. Further, we will continue to evaluate the appropriateness of payment for these patients as we do all other technologies and patient categories.

Comment: One commenter objected to the reference to Zyvox™ sales figures as evidence of expanding general access to the drug. The commenter stated that we provided no evidence to indicate this sale growth is the result of expanding use in the treatment of Medicare beneficiaries. The commenter went on to argue that “sales reports and other company financial data must be considered outside the scope of the review process.”

Response: We disagree that we should ignore sales reports related to a product seeking additional payments to promote its expansion into the medical market. This market analysis was certainly not the basis for our decision not to approve this applicant, as described above. The sales reports were simply a portion of data we considered in our evaluation of the effects of our decision. We also note

that we received no evidence during the comment period to document that the sales growth referenced above did not pertain to Medicare beneficiaries.

Comment: The applicant expressed concern that, during discussions and meetings with CMS, no mention was made that there might be an issue related to the application meeting the "new" criterion.

Response: The criteria to qualify for add-on payments were specified clearly in the September 7, 2001 final rule. Clearly, the applicant believed it met the criteria, as evidenced by the fact that it applied and its subsequent comments on our proposed decision. The facts regarding the point at which Zyvox™ was approved by the FDA and when it became available for use are agreed upon. The difference of opinion centers on the criteria for "new". The commenter has described its interpretation, with which we disagree, as discussed above. The public comment process is part of the review and approval process. We believe the public comment process is the most appropriate avenue to consider the interpretation of legislative and regulatory criterion. As discussed above, we do not believe that it would be appropriate to allow technologies that have already been in use to attain higher payments as a result of the assignment of a new, more specific, ICD-9-CM code.

d. Renew™ Radio Frequency Spinal Cord Stimulation Therapy

An application was submitted by Advanced Neuromodulation Systems (ANS) for the Renew™ Spinal Cord Stimulation Therapy for approval as a new technology eligible for add-on payments. ANS is a medical device company that deals with management of chronic pain that is severe, persistent, and unresponsive to drugs or surgery. Spinal cord stimulation (SCS) offers a treatment alternative to expensive ongoing comprehensive care. Renew™ SCS was introduced in July 1999 as a device for the treatment of chronic intractable pain of the trunk and limbs.

According to the applicant:
 "SCS is a reversible method of pain control that works well for certain types of chronic intractable pain. SCS requires a surgical procedure to implant a receiver and leads. These implanted devices generate electrical stimulation that interrupts pain signals to the brain. SCS is considered to be a treatment of last resort, and is usually undertaken only when first and second-line therapies for chronic pain fail to provide adequate relief. SCS uses low-intensity electrical impulses to trigger nerve

fibers selectively along the spinal cord. The stimulation of these nerve fibers diminishes or blocks the intensity of the pain message being transmitted to the brain. SCS replaces areas of intense pain with a more pleasant sensation * * *," masking the pain that is normally present.

Prior to Renew™, SCS systems offered few technical capabilities for treating complex chronic pain patients who suffered with pain that spanned noncontiguous areas (multi-focal) or that varied in intensity over the painful area. The Renew™ system features a multiplex output mode that controls separate stimulation programs to allow outputs of varying frequencies to be used at the same time. According to ANS, "The significance of this technology is that it is now possible to multiplex (link and cycle) up to 8 programs to provide pain relieving paresthesia overlap of anatomical regions that are not contiguous or that cannot be captured by a single program."

The Renew™ technology also allows the concomitant use of separate programs for patients who require different power settings for different areas that have pain. With this technology, separate programs can be programmed from the same unit, with electrical output parameters customized for each painful region. ANS contends that the clinical significance of this technology is that patients who find satisfactory pain relief will require fewer alternative treatments to treat unrelieved pain.

The ANS application specifically requests add-on payments for the costs of the Radio Frequency System (RF System). This system only requires one surgical placement and does not require additional surgeries to replace batteries as do other internal SCS systems. ANS estimates that there are 2,900 RF Systems implanted annually; only 10 percent are in the inpatient setting. ANS is the only company that offers a 16-channel/electrode system.

ANS provided the 2001 hospital acquisition cost for ANS Renew™ 8 and 16 Channel/Electrode RF SCS Systems as follows:

	ANS 2001 list price
8 Channel/Electrode System:	
One Lead (8 Electrode)	\$2,750.00
One Extension (8 Electrode) ..	695.00
Receiver (8 Channel)	4,995.00
Transmitter (8 Channel)	4,995.00
Total System	13,435.00
16 Channel/Electrode System:	
Two Leads (16 electrode)	5,550.00
Two Extensions (16 electrode)	1,390.00

	ANS 2001 list price
Receiver (16 Channel)	7,295.00
Transmitter (16 Channel)	7,295.00
Total System	21,480.00

Currently, implanting the ANS 8 or 16 Channel/Electrode SCS System falls into DRG 4 (Spinal Procedures) under ICD-9-CM procedure code, 03.93 (Insertion or replacement, spinal neurostimulation). According to the September 7, 2001 **Federal Register**, the threshold to qualify for additional new technology payments for services classified to DRG 4 would be \$38,242 (based on adding the geometric mean and the standard deviation of standardized charges) (66 FR 46922).

Relative to hospital invoice information, ANS provided the following estimates:

" * * * 90% of the U.S. hospital cost-to-charge ratios fall between .24 and .69, and 75% fall between .29 and .58. The median is .41. This median costs-to-charge ratio equates to an average hospital markup of 144%. If you apply the average hospital markup of 144% to the device acquisition cost plus the estimated facility cost, the result is an estimated hospital invoice for the SCS implant procedure of \$40,101.00, for the 8 Channel/Electrode System and \$59,731.00 for the 16 Channel/Electrode System."

In support of its application, ANS provided detailed bills for 12 patients. Of the 12 cases with detailed billing data, 3 patients were age 65 or older. The average total charge for these 3 cases, including the average standardized charge for operating room costs, was \$42,820.

As noted previously, technology will no longer be considered new after the costs of the technology are reflected in the DRG weights. Because the Renew™ RF System was introduced in July 1999, the FY 2001 MedPAR data used to calculate the DRG weights for FY 2003 includes any Medicare cases that involved the implantation of the Renew™ RF System. The charges associated with these cases are reflected in the FY 2003 DRG weights. Therefore, the Renew™ RF System is not considered "new" under our criteria. However, we will continue to monitor these cases in DRG 4 to determine whether this is the most appropriate DRG assignment.

Comment: Several commenters objected to our proposed decision to not approve this application because the technology does not meet our criterion for "new" designation.

Response: We continue to believe that this technology does not meet the criterion for the reasons given in the proposed rule, as elaborated on in our response to comments discussed above in relation to Zyvox™.

III. Changes to the Hospital Wage Index

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts “for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.” In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by the Office of Management and Budget (OMB). OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs since they allow a more precise breakdown of labor costs. If a metropolitan area is not designated as part of a PMSA, we use the applicable MSA. Rural areas are areas outside a designated MSA, PMSA, or NECMA. For purposes of the wage index, we combine all of the rural counties in a State to calculate a rural wage index for that State.

We note that, effective April 1, 1990, the term Metropolitan Area (MA) replaced the term MSA (which had been used since June 30, 1983) to describe the set of metropolitan areas consisting of MSAs, PMSAs, and CMSAs. The terminology was changed by OMB in the March 30, 1990 **Federal Register** to distinguish between the individual metropolitan areas known as MSAs and the set of all metropolitan areas (MSAs, PMSAs, and CMSAs) (55 FR 12154). For purposes of the prospective payment system, we will continue to refer to these areas as MSAs.

Under section 1886(d)(8)(B) of the Act, hospitals in certain rural counties adjacent to one or more MSAs are considered to be located in one of the adjacent MSAs if certain standards are met. Under section 1886(d)(10) of the Act, the Medicare Geographic

Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification from a rural area to a MSA, one rural area to another rural area, or from one MSA to another MSA, for purposes of payment under the acute care hospital inpatient prospective payment system.

In a December 27, 2000 notice published in the **Federal Register** (65 FR 82228), OMB issued its revised standards for defining MSAs. In that notice, OMB indicated that it plans to announce in calendar year 2003 definitions of MSAs based on the new standards and the Census 2000 data. We will evaluate the new area designations and their possible effects on the Medicare wage index, as well as other provider payment implications. Although the final construct of the redefined MSAs will not be known until 2003, we intend to work closely with OMB to begin to assess the potential ramifications of these changes.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey should measure, to the extent feasible, the earnings and paid hours of employment by occupational category, and must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. As discussed below in section III.F. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating the wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to provide for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. The initial collection of these data must be completed by September 30, 2003, for application beginning October 1, 2004 (the FY 2005 wage index).

In the May 4, 2001 proposed rule (66 FR 22674), we suggested possible occupational categories from the Occupational Employment Statistics (OES) survey conducted by the Bureau of Labor Statistics. In response to comments on the proposed rule, we agreed to work with the health care industry to develop a workable data collection tool. After we develop a method that appropriately balances the need to collect accurate and reliable

data with the need to collect data that hospitals can be reasonably expected to have available, we will issue instructions as to the type of data to be collected, in advance of actually requiring hospitals to begin providing the data.

Comment: Commenters strongly encouraged us to take the time needed to develop the most appropriate survey instrument for collecting occupational mix data and to provide adequate time for hospitals to have available the required information. One commenter wrote that neither CMS nor the hospital industry is ready to implement an occupational mix adjustment. The commenter believed that, when the law was passed requiring occupational mix data to be collected by the end of September 2003, Congress did not understand the burden and complexity of collecting and using the information. The commenter noted that, over 10 years, CMS encountered many problems when it first tried to collect occupational mix data and believed that, today, hospitals are in no better position to provide the necessary information.

A commenter also requested that we publish a rule for comment that delineates our proposed occupational mix methodology and illustrates how the index mix would be calculated and used to adjust the overall wage index. The commenter expressed interest in continuing to work with us on this effort.

MedPAC has recommended that CMS collect the occupational mix data as part of the Medicare cost report, just as the wage data are currently collected. MedPAC notes that a separate survey usually has a lower initial response rate, and incorporating the survey as part of the cost report should minimize reporting burden on hospitals, enhance data accuracy, and help to achieve a 100-percent response rate. MedPAC recommended that we modify the cost report form and instructions as soon as possible to enable the collection of this data during the second round of data collection. MedPAC also recommended that we provide detailed information as soon as possible to hospitals regarding the specific occupational mix data they will be required to report in order to allow hospitals time to modify their information systems to collect the necessary wage and hours data. Although, MedPAC acknowledges it may not be possible to collect accurate data for FY 2002, it believes that it still may be feasible to collect the data for FY 2003 and meet the Congressional mandate to implement an occupational

mix adjustment for the FY 2005 wage index.

A few commenters expressed concern that an occupational mix adjustment would only recognize geographical differences in the price hospitals pay for a particular employee category and would not reflect that a hospital, such as a teaching hospital, may have higher labor costs because its patient population requires a larger number of highly skilled, highly priced employees. The commenters noted that a previous MedPAC study showed that an occupational mix adjustment would lower the wage index values for many areas where teaching hospitals are located. The commenters also expressed concern that Medicare's current DRG payment system does not adequately recognize patient severity and the higher resource costs that are associated with treating complex patients. The commenters believed that the current wage index methodology more appropriately reflects a higher employee skill mix, as reflected in higher wage indices where teaching hospitals are located, allowing teaching hospitals to recoup some of the losses they incur under the current DRG system. The commenters suggested that, if we include an occupational mix adjustment in the wage index, we should also refine the DRG system to ensure that more complex cases are adequately reimbursed.

Response: We appreciate all the comments we received and the continued support and assistance of hospitals in developing the occupational mix adjustment. Before implementing the adjustment, we will publish the details of the occupational mix methodology in the **Federal Register** and provide for public comment.

B. FY 2003 Wage Index Update

The FY 2003 wage index values in section V. of the Addendum to this final rule (effective for hospital discharges occurring on or after October 1, 2002 and before October 1, 2003) are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 1999 (the FY 2002 wage index was based on FY 1998 wage data).

The final FY 2003 wage index includes the following categories of data associated with costs paid under the hospital inpatient prospective payment system (as well as outpatient costs), which were also included in the FY 2002 wage index:

- Salaries and hours from short-term, acute care hospitals.
- Home office costs and hours.

- Certain contract labor costs and hours.

- Wage-related costs.

Consistent with the wage index methodology for FY 2002, the wage index for FY 2003 also continues to exclude the direct and overhead salaries and hours for services such as skilled nursing facility (SNF) services, home health services, and other subprovider components that are not paid under the hospital inpatient prospective payment system.

We calculate a separate Puerto Rico-specific wage index and apply it to the Puerto Rico standardized amount. (See 62 FR 45984 and 46041.) This wage index is based solely on Puerto Rico's data. Finally, section 4410 of Public Law 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is not located in a rural area may not be less than the area wage index applicable to hospitals located in rural areas in that State.

C. FY 2003 Wage Index

1. Removal of Wage Costs and Hours Related to Graduate Medical Education (GME) and Certified Registered Nurse Anesthetists (CRNAs)

Because the hospital wage index is used to adjust payments to hospitals under the acute care hospital inpatient prospective payment system, the wage index should, to the extent possible, reflect the wage costs associated with those cost centers and units paid under the hospital inpatient prospective payment system. Costs related to graduate medical education (GME) (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs) are paid by Medicare separately from the hospital inpatient prospective payment system. In 1998, the AHA convened a workgroup to develop a consensus recommendation on this issue. The workgroup, which consisted of representatives from national and State hospital associations, recommended that costs related to GME and CRNAs be phased out of the wage index calculation over a 5-year period. Based upon our analysis of hospitals' FY 1996 wage data, and consistent with the AHA workgroup's recommendation, we specified in the July 30, 1999 final rule (64 FR 41505) that we would phase out these costs from the calculation of the wage index over a 5-year period, beginning in FY 2000.

FY 2003 would be the fourth year of the phaseout. Therefore, the wage index calculation for FY 2003 would blend 20 percent of a wage index with GME and CRNA costs included and 80 percent of

a wage index with GME and CRNA costs removed. FY 2004 would begin the calculation with 100 percent of the GME and CRNA costs removed. However, in the May 9, 2002 proposed rule, we proposed to remove 100 percent of GME and CRNA costs from the FY 2003 wage index.

We have analyzed the FY 2003 wage index both with 100 percent of GME and CRNA costs removed and with 80 percent of these costs removed used the final wage index file. We found that the majority of labor market areas, both rural and urban, would benefit by the removal of all of these costs (304 out of 373). Only one rural labor market area would be negatively impacted by this change (New Hampshire by -0.09 percent). We note that, as part of its Report to the Congress on Medicare in Rural America (June 2001), MedPAC recommended fully implementing this phaseout during FY 2002. Similar to our findings, MedPAC found the effect of completely eliminating GME and CRNA costs "might not be negligible for some areas, but it would not be large in any case" (page 76). Of the urban labor market areas that would be negatively affected the decreases range from .01 to 1.0 percent.

Because we believe removing GME and CRNA costs from the wage index calculation is appropriate, and the impact is generally positive and relatively small, we proposed to remove 100 percent of GME and CRNA costs beginning with FY 2003 wage index.

Comment: Several commenters stated that, although the early elimination of GME and CRNA costs from the wage index calculation is not as significant as some other payment reductions, the proposed policy represents a net reduction in payments for some hospitals compared to payments using a wage index with 80 percent of GME and CRNA costs removed. Based on CMS' analysis presented in the proposed rule, the commenters noted that excluding 100 percent of these costs from the FY 2003 wage index would negatively affect hospitals in more than 20 percent of the labor market areas. Commenters also noted that the affected areas are primarily urban, where large teaching hospitals are more likely to be located. In addition, the commenters noted that urban hospitals have to absorb increased indigent care costs.

The commenters believed that our current 5-year phaseout policy was the result of a good-faith agreement negotiated with a hospital industry workgroup. They further believed that adoption of the proposed accelerated phaseout for the FY 2003 wage index would establish an unfortunate

precedent that questions the rationale for hospital associations to enter into any future negotiations with CMS. The commenters request us to adhere to our original 5-year phaseout schedule.

One commenter supported our proposal to remove 100 percent of GME and CRNA costs from the FY 2003 wage index.

Response: We implemented changes to the FY 1995 cost report (used to calculate the FY 1999 wage index) in order to separately identify the wage data associated with GME and CRNAs. However, due to data reporting problems, we were unable to remove these costs until the FY 2000 wage index. In the meantime, the hospital industry established a workgroup that developed a compromise agreement on the removal of these data from the wage index, including a 5-year phaseout to alleviate the negative impact this change would have on some areas. The recommendations of the workgroup were presented to CMS, and most (but not all) of them were accepted (see the July 30, 1999 final rule, 64 FR 41505). However, we note that CMS was not a party to the industry workgroup that developed the compromise agreement.

As noted above, Medicare pays hospitals for GME and CRNA costs separately from the acute care hospital inpatient prospective payment system. CMS is responsible for ensuring the accuracy and fairness of the wage index and it is our assessment at this time that, due to the small impact as described above, of removing GME and CRNA costs from the wage index, and because hospitals that are negatively impacted by this change are in areas that have benefited from the inclusion of these costs over the years, it is in the interest of improving the overall fairness of the wage index to accelerate the phaseout. Therefore, we are proceeding with removing 100 percent of GME and CRNA costs beginning with the FY 2003 wage index.

Comment: One commenter representing CRNAs requested that we continue to include in the wage index the costs of contract CRNAs who are used by hospitals to address staffing shortages. The commenters noted that our proposal recognizes the fact that hospitals are increasingly reliant upon contract labor for providing direct and indirect patient care. The commenter believed that hospitals should not be penalized for having to use contract CRNAs to meet staffing needs.

Response: As explained above, we believe the wage index should, to the extent possible, reflect those costs for which hospitals receive payment under the acute care hospital inpatient

prospective payment system. Because hospitals are not paid under this system for CRNAs' services, we continue to believe that CRNA costs are appropriately excluded from the wage index.

2. Contract Labor for Indirect Patient Care Services

Our policy concerning the inclusion of contract labor costs for purposes of calculating the wage index has evolved with the increasing role of contract labor in meeting special personnel needs of many hospitals. In addition, improvements in the wage data have allowed us to more accurately identify contract labor costs and hours. As a result, effective with the FY 1994 wage index, we included the costs for direct patient care contract services in the wage index calculation, and with the FY 1999 wage index, we included the costs for certain management contract services. (The August 30, 1996 final rule (61 FR 46181) provided an in-depth discussion of the issues related to the inclusion of contract labor costs in the wage index calculation.) Further, the FY 1999 wage index included the costs for contract physician Part A services, and the FY 2002 wage index included the costs for contract pharmacy and laboratory services.

We continue to consider whether to expand our contract labor definition to include more types of contract services in the wage index. In particular, we have examined whether to include the costs for acquired dietary and housekeeping services, as many hospitals now provide these services through contracts. Costs for these services tend to be below the average wages for all hospital employees. Therefore, excluding the costs and hours for these services if they are provided under contract, while including them if the services are provided directly by the hospital, creates an incentive for hospitals to contract for these services in order to increase their average hourly wage for wage index purposes.

It has also been suggested that we expand our definition to include all contract services, including both direct and indirect patient care services, in order to more appropriately calculate relative hospital wage costs. Our goal is to ensure that our wage index policy continues to be responsive to the changing need for contract labor and allow those hospitals that must depend on contract labor to supply needed services to reflect those costs in their wage data. At the same time, we are concerned about hospitals' ability to provide documentation that sufficiently

details contract costs and hours. The added overhead, supplies, and miscellaneous costs typically associated with contract labor may result in higher costs for contract labor compared to salaried labor. If these costs are not separately identifiable and removed, they may cause distortions in the wage index.

We agree that it may be appropriate to include indirect patient care contract labor costs in the wage index. However, in light of concerns about hospitals' ability to accurately document and report these costs, we believe the best approach is to assess and include these costs incrementally. Through incremental changes, we can better determine the impact that specific costs have on area wage index values. Also, by including these costs incrementally, hospitals and fiscal intermediaries are able to adjust to the additional documentation and review requirements associated with reporting the additional contract costs and hours.

In the May 9, 2002 proposed rule, we proposed to begin collecting contract labor costs and hours for management services and the following overhead services: administrative and general, housekeeping, and dietary. We selected these three overhead services because they are provided at all hospitals, either directly or through contracts, and together they comprise about 60 percent of a hospital's overhead hours. In addition, consistent with our consideration of administrative and general services, we proposed to collect costs and hours associated with contract management services that are not currently included on Worksheet S-3, Part II, Line 9 (that is, management services other than those of the chief executive officer, chief financial officer, chief operating officer, and nurse administrator).

Comment: Several commenters supported our continuing efforts to examine contract labor costs for inclusion in the wage index and to ensure that the wage index is not manipulated to distort an area's wage level. MedPAC commented that "excluding contract labor costs may affect the accuracy of the wage index and introduces undesirable incentives that may affect hospital employment decisions." However, some commenters cautioned that it will be challenging for hospitals to provide the required detailed data and documentation for the appropriate costs and hours and to exclude nonlabor expenses, such as equipment and supplies, from total contract expenses. The commenters believed that, for most housekeeping and dietary services contracts,

meaningful data regarding hours are nonexistent. For management contracts, some commenters believed that the collection of cost and hours data may be more feasible. However, the contract itself may not provide enough detail to be a sufficient source of documentation. One commenter disagreed with the inclusion of contract labor costs in the administrative and general cost center because the commenter believed that the types of costs reported in that center vary too widely across hospitals to be comparable.

The commenters advised that it is important for us to ensure consistency among fiscal intermediaries in their auditing of supporting documentation for contract labor. Further, some commenters supported a delay in including the additional contract labor costs until we develop clear definitions and acceptable methods for tracking the costs and hours. A delay would also allow hospitals more time to assure the appropriate and accurate collection of the required data. One commenter also requested that CMS make the new data regarding contract labor costs available for review, analysis, and comment prior to including these costs in the wage index.

Response: Due to, among other things, the general support we received for our proposal to include costs for contract indirect patient care services in the wage index, we are proceeding as proposed. We will revise the cost report form and instructions, as early as it is feasible to do so. We also will monitor the hospital industry for information regarding hospitals' ability to provide the data. Further, we will work with hospitals and intermediaries to develop acceptable methods for tracking the costs and hours. Finally, before including these additional costs in the wage index, we will provide a detailed analysis of the impact of including these additional costs in the wage index values in the **Federal Register** and provide for public comment. Our final decision on whether to include contract indirect patient care labor costs in our calculation of the wage index will depend on the outcome of our analyses and public comments.

Comment: One commenter believed that, in order to be a true measure of labor market differences, the wage index should reflect only those jobs and employment practices that are the same in every geographic area. In addressing the disparity in the current wage index policy that excludes the costs for contracted low paying jobs from the wage index, while the costs for the same services under direct hire are included, the commenter suggested that we

consider excluding from the wage index all labor costs that are obtained under different methods across hospitals.

Response: The use of contract labor is widespread among hospitals, and the practice of hiring under contract exists to some degree in virtually every service a hospital provides. Under the commenter's proposal, the resulting wage index would reflect too few categories of services to be representative of hospitals' labor force. Therefore, we believe it would not be feasible to exclude from the wage index all services that are obtained by hospitals using different employment methods.

D. Verification of Wage Data From the Medicare Cost Report

The data for the FY 2003 wage index were obtained from Worksheet S-3, Parts II and III of the FY 1999 Medicare cost reports. The data file used to construct the wage index includes FY 1999 data submitted to us as of July 2002. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries to revise or verify data elements that resulted in specific edit failures. The unresolved data elements that were included in the calculation of the proposed FY 2003 wage index have been resolved and are reflected in calculation of the final FY 2003 wage index.

The final rule we removed data for 36 hospitals that failed edits. For 14 of these hospitals, we were unable to obtain sufficient documentation to verify or revise the data because the hospitals are no longer participating in the Medicare program, are under new ownership, or are in bankruptcy status, and supporting documentation is no longer available. We identified 22 hospitals with incomplete or inaccurate data resulting in zero or negative, or otherwise aberrant, average hourly wages. Therefore, the hospitals were removed from the calculation. As a result, the final FY 2003 wage index is calculated based on FY 1999 wage data for 4,797 hospitals.

Comment: One commenter requested that we remove the data from the FY 2003 wage index calculation for a specific hospital that closed in 2001. According to the commenter, the hospital had a major accounting and recordkeeping problem dating back several years.

Response: We have always maintained, subject to limited expectations, that any hospital that is in operation during the data collection

period used to calculate the wage index should be included in the database, since the hospital's data reflect conditions occurring in that labor market area during the period surveyed (59 FR 45353). While we also believe it is appropriate to eliminate data for terminated hospitals when there is reason to believe that the data are incorrect, and the data cannot be verified due to the hospital's closure, if the wage data for a terminated hospital does not fail any of our edits for reasonableness, the hospital's data are included in the calculation of the area's wage index.

During FY 1999, the period used to calculate the FY 2003 wage index, the hospital in question was the second largest hospital in its MSA. We find the hospital's FY 1999 Worksheet S-3 wage data to be consistent with hospitals of similar size in the MSA. Therefore, we will retain the wage data for the closed hospital in the FY 2003 wage index. We also note that removing the hospital's data from the wage index calculation would actually lower the MSA's wage index value.

Comment: One commenter representing a national hospital association requested that CMS add a fatal edit to the cost reporting systems to eliminate obvious errors that are difficult or impossible to correct 4 years later when we use the data for the wage index. Examples of such errors are negative average hourly wages or a line item that includes salaries but no associated hours. Currently, we delete the problematic data elements, but the commenter believed that this does not necessarily make the reported data better, nor does it make the data consistent with data reported by other hospitals. The commenter recommended that we include a fatal edit that will not allow the cost report to be filed by the hospital until all required wage data have been entered.

Response: We agree with the commenter that these obvious errors should be corrected by the hospital before the cost report is filed. The cost reporting system currently has an edit that prevents the reporting of negative adjusted salaries. Therefore, no line item should have a negative average hourly wage. However, due to the complexities of the cost report software, a hospital is unable to simply adjust Worksheet S-3, Part II salaries to zero, if hours are missing or inaccurate, without also triggering a necessary adjustment to the trial balance (Worksheet A), as most salary items reported on Worksheet S-3, Part II are directly transferred from Worksheet A. Because Worksheet S-3, Part II wage

data are only used for wage index purposes, we believe it is preferable for both CMS and hospitals not to have the entire cost report rejected, and risk an untimely submission of the cost report, because the hours on Worksheet S-3, Part II are problematic.

We are working on revising the intermediaries' software to improve their edits and give them more flexibility to make adjustments directly to Worksheet S-3, Part II when the adjustments are necessary for wage index purposes only. We acknowledge that this revision would not help hospitals to detect obvious errors as early as possible, that is, before they file their cost reports with their intermediaries. However, improved intermediary edits would allow the errors to be identified and corrected before the data are submitted to us to be used in developing the wage index.

E. Computation of the FY 2003 Wage Index

The method used to compute the final FY 2003 wage index follows.

Step 1—As noted above, we based the FY 2003 wage index on wage data reported on the FY 1999 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S-3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 1998 and before October 1, 1999. In addition, we included data from some hospitals that had cost reporting periods beginning before October 1998 and reported a cost reporting period covering all of FY 1999. These data were included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 1999 data. We note that, if a hospital had more than one cost reporting period beginning during FY 1999 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 1998 and before October 1, 1999), we included wage data from only one of the cost reporting periods, the longest, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the latest period in the wage index calculation.

Step 2—Salaries—Beginning with the FY 2003 wage index, the method used to compute a hospital's average hourly wage excludes all GME and CRNA costs.

In calculating a hospital's average salaries plus wage-related costs, we subtracted from Line 1 (total salaries) the GME and CRNA costs reported on lines 2, 4.01, and 6, the Part B salaries reported on Lines 3 and 5, home office salaries reported on Line 7, and excluded salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the acute care hospital inpatient prospective payment system). We also subtracted from Line 1 the salaries for which no hours were reported on Line 4. To determine total salaries plus wage-related costs, we added to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9, 9.01, 9.02, and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no corresponding hours are reported were not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 18) are excluded if no corresponding salaries are reported for those employees on Line 4.

Step 3—Hours—With the exception of wage-related costs, for which there are no associated hours, we computed total hours using the same methods as described for salaries in Step 2.

Step 4—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocated overhead costs to areas of the hospital excluded from the wage index calculation. First, we determined the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S-3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 6, 7, and Part III, Line 13 of Worksheet S-3). We then computed the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S-3, Part III. Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, and 7); (2) we computed overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, and 18; and (3) we multiplied the computed overhead wage-related costs

by the above excluded area hours ratio. Finally, we subtracted the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5—For each hospital, we adjusted the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimated the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 1998 through April 15, 2000 for private industry hospital workers from the Bureau of Labor Statistics' *Compensation and Working Conditions*. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/98	11/15/98	1.04550
11/14/98	12/15/98	1.04325
12/14/98	01/15/99	1.04111
01/14/99	02/15/99	1.03880
02/14/99	03/15/99	1.03632
03/14/99	04/15/99	1.03369
04/14/99	05/15/99	1.03092
05/14/99	06/15/99	1.02801
06/14/99	07/15/99	1.02509
07/14/99	08/15/99	1.02230
08/14/99	09/15/99	1.01962
09/14/99	10/15/99	1.01687
10/14/99	11/15/99	1.01385
11/14/99	12/15/99	1.01056
12/14/99	01/15/00	1.00710
01/14/00	02/15/00	1.00358
02/14/00	03/15/00	1.00000
03/14/00	04/15/00	0.99638

For example, the midpoint of a cost reporting period beginning January 1, 1999 and ending December 31, 1999 is June 30, 1999. An adjustment factor of 1.02509 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 1999 and covered a period of less than 360 days or more than 370 days, we annualized the data to reflect a 1-year

cost report. Annualization is accomplished by dividing the data by the number of days in the cost report and then multiplying the results by 365.

Step 6—Each hospital was assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B) or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7—We divided the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8—We added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the nation and then divided the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the national average hourly wage is \$23.2295.

Step 9—For each urban or rural labor market area, we calculated the hospital wage index value by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10—Following the process set forth above, we developed a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly wage as described above.) We added the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divided the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall average hourly wage of \$11.0086 for Puerto Rico. For each labor market area in Puerto Rico, we calculated the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11—Section 4410 of Public Law 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Furthermore, this wage index floor is to be implemented

in such a manner as to ensure that aggregate prospective payment system payments are not greater or less than those that would have been made in the year if this section did not apply. For FY 2003, this change affects 180 hospitals in 39 MSAs. The MSAs affected by this provision are identified by a footnote in Table 4A in the Addendum of this final rule.

Comment: Two commenters opposed our use of 3-year-old data for developing the wage index. The commenters believed that the FY 2003 wage index does not reflect current market conditions for nurses. For example, one commenter stated that, due to the current nursing shortage, her facility's average hourly wage has increased 10 percent over the past 18 months. However, the wage index does not adequately reflect the increased wage costs. The commenter noted that rural hospitals have been severely impacted by the nursing shortage. Since rural hospitals are reliant upon Medicare reimbursement, the commenter suggested that we revise the wage index methodology to allow the wage index to reflect labor cost increases sooner.

Response: The wage index is a relative measure, which compares area average hourly wages to the national average hourly wage. The nursing shortage and increased nursing wages are a national phenomenon. We believe the wage index is minimally impacted by inflationary effects of increased nursing costs. Increases in hospital wages overall would be reflected in the market basket.

In computing the wage index, we use data from cost reports beginning during the most recent Federal fiscal year for which we have a complete year's worth of data. For the FY 2003 wage index, that is cost reports that began during FY 1999. Because hospitals' cost reports may end as late as August or even September of the following year, it would not be feasible for us to use cost reports that began during FY 2000 (many of which would not close until the latter part of 2001). Due to the time period allowed for: (1) Hospitals to complete and submit their cost reports to their intermediaries; (2) intermediaries to perform a separate, detailed review of all hospitals' wage data and submit the results to CMS; and (3) CMS to compile a complete set of all hospitals' wage data from a given Federal fiscal year, it would not be possible to use FY 2000 cost report data to calculate the FY 2003 wage index. As described in the proposed rule (67 FR 31434) and section III.E. of this final rule, we adjust the wage index to a common period that reflects the latest

cost reporting period for the filing year. For the FY 2003 wage index, this period is September 1, 1999 to August 31, 2000.

Comment: One commenter recommended that, to reflect the labor markets in which rural hospitals compete more accurately, the wage index value for a rural area should be the average of the three lowest MSA rates in the geographic area.

Response: We note that the statute requires that we apply wage indexes that reflect "the relative hospital wage level in the geographic area of the hospital" (section 1886(d)(3)(E) of the Act). Furthermore, in some States, there are some MSAs for which the calculated wage index value is actually lower than the rural area of the state. As we discussed in the proposed rule (67 FR 31435) and in section III.E. of this final rule, for those urban areas, we assign the statewide rural wage index value. We are uncertain as to whether the commenter considered this policy in its recommendation. While the commenter did not provide details of its rationale for the recommended change, we appreciate the commenter's suggestion and welcome a more detailed discussion and analysis.

Comment: One commenter wrote that CMS' instructions for developing wage-related costs using Generally Accepted Accounting Principles (GAAP) are inconsistently communicated by CMS staff and inconsistently applied by the fiscal intermediaries. The commenter urged us to ensure the credibility of the wage index by requiring that our staff and contractors understand and consistently apply our wage index policies to eliminate variations in interpretation and application of the wage data.

Response: In an effort to clarify our instructions and to promote consistency in hospitals' reporting and CMS' and the intermediary's handling of wage-related costs that are developed using GAAP, we have revised the cost report instructions (in Transmittals 8 and, soon to be released, 9) and the intermediary's desk review program. Because of the wide variation in GAAP methodologies, we continue to emphasize that it is the responsibility of the hospitals to be able to provide adequate support for the GAAP methodologies they apply. In addition, if a hospital believes that an intermediary may be incorrectly handling a particular issue, the hospital is encouraged to bring it to our attention. We will continue our efforts to ensure uniform reporting of the wage data.

Comment: One commenter, representing the District of Columbia,

indicated that the Washington, DC–MD–VA–WV MSA includes 16 Virginia hospitals, 13 Maryland hospitals, 12 District of Columbia hospitals, and 2 West Virginia hospitals. The commenter was concerned about the negative impact of the West Virginia and Maryland hospitals on the Washington, DC–MD–VA–WV MSA wage index (although the commenter did not specify a particular issue with the West Virginia hospitals). Unlike hospitals in all other States and the District of Columbia, Maryland hospitals, which are under a waiver from the acute inpatient prospective payment system, do not rely on the wage index adjustment factor to adjust their inpatient Medicare payments. Therefore, the commenter wrote, Maryland hospitals have no incentive to accurately report their wage costs on the Medicare cost report or to review and request corrections to CMS' wage index public use files. The commenter requested us to carefully review the impact of Maryland's all-payor system on hospitals within the same MSA.

Response: As the commenter notes, Maryland hospitals are paid under a program waiver (section 1814(b)(3) of the Act), in which the State establishes hospital inpatient and outpatient payment rates for Medicare, Medicaid, and private payors. The Medicare wage index is not a factor in the State's ratesetting methodology. However, in recent years the wage index has been applied to the Medicare payment rates for other providers that are not under the State's waiver, such as SNFs, hospices, and home health agencies. Many Maryland hospitals own, or are members of systems that own, facilities or entities that are now directly impacted by the quality of the hospitals' reported data.

As with all hospitals in the wage index, we edited the FY 1999 wage data for the Maryland and West Virginia hospitals. We found no significant problems in their wage data. We believe that the Maryland hospitals' wage data are reasonable for the State and the MSA. The lower average hourly wages for the West Virginia hospitals are comparable to other hospitals in that State. Furthermore, under OMB's definition of the Washington, DC–MD–VA–WV MSA, these Maryland and West Virginia hospitals are part of that MSA. Therefore, the wage data for these hospitals will continued to be used in the calculation of the area wage index for the Washington DC–MD–VA–WV MSA.

F. Revisions to the Wage Index Based on Hospital Redesignation

1. General

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the prospective payment system. Hospitals can elect to reclassify for the wage index or the standardized amount, or both, and as individual hospitals or as rural groups. Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. Hospitals must apply for reclassification to the MGCRB, which issues its decisions by the end of February for reclassification to become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are in §§ 412.230 through 412.280.

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with FY 2001, a MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 fiscal years, unless the hospital elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of the Act provides that the MGCRB must use the 3 most recent years' average hourly wage data in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year.

Section 304(b) of Public Law 106–554 provides that, by October 1, 2001, the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a single wage index, for reclassifications beginning in FY 2003.

Beginning October 1, 1988, section 1886(d)(8)(B) of the Act permits a hospital located in a rural county adjacent to one or more urban areas to be designated as being located in the MSA to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area under the standards published in the **Federal Register** on January 3, 1980 (45 FR 956) for designating MSAs (and for designating NECMAs), and if the commuting rates used in determining outlying counties (or, for New England, similar recognized area) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under

the standards, from) the central county or counties of all contiguous MSAs (or NECMAs). Hospitals that met the criteria using the January 3, 1980 version of these OMB standards were deemed urban for purposes of the standardized amounts and for purposes of assigning the wage index.

Section 402 of Public Law 106–113 provided that, for FYs 2001 and 2002, hospitals could elect whether to apply standards developed by OMB in 1980 or 1990 in order to qualify for redesignation under section 1886(d)(8)(B) of the Act. In accordance with section 1886(d)(8)(B)(ii)(II) of the Act, in the May 9, 2002 proposed rule, we proposed that, beginning with FY 2003, redesignation under section 1886(d)(8)(B) of the Act will be based on the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census.

2. Effects of Reclassification

The methodology for determining the wage index values for redesignated hospitals is applied jointly to the hospitals located in those rural counties that were deemed urban under section 1886(d)(8)(B) of the Act and those hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. Therefore, as provided in section 1886(d)(8)(C) of the Act, the wage index values were determined by considering the following:

- If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.

- If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.

- If including the wage data for the redesignated hospitals increases the wage index value for the area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value.

- The wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.
- Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred.
- Rural areas whose wage index values increase as a result of excluding the wage data for the hospitals that have been redesignated to another area have their wage index values calculated exclusive of the wage data of the redesignated hospitals.
- The wage data for a reclassified urban hospital is included in both the wage index calculation of the area to which the hospital is reclassified (subject to the rules described above) and the wage index calculation of the urban area where the hospital is physically located.

The wage index values for FY 2003 are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this final rule. Hospitals that are redesignated should use the wage index values shown in Table 4C. Areas in Table 4C may have more than one wage index value because the wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

Tables 3A and 3B in the Addendum of this final rule list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FYs 1997, 1998, and 1999 wage data. Table 3A lists these data for urban areas and Table 3B lists these data for rural areas. In addition, Table 2 in the Addendum to this final rule includes the adjusted average hourly wage for each hospital from the FY 1997 and FY 1998 cost reporting periods, as well as the FY 1999 period used to calculate the FY 2003 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period.

We indicated in the proposed rule that, at the time the proposed wage index was constructed, that the MGCRB had completed its review of FY 2003 reclassification requests. Table 9 of this final rule shows hospitals that have been reclassified under either section

1886(d)(8)(B) or section 1886(d)(10)(D) of the Act. This table includes hospitals reclassified for FY 2003 by the MGCRB, as well as hospitals that were reclassified for the wage index in either FY 2001 or FY 2002 and are, therefore, in either the third or second year of their 3-year reclassification. This table also includes hospitals reclassified for purposes of the standardized amount and hospitals located in urban areas that have been designated rural in accordance with section 1886(d)(8)(E) of the Act. There are 54 hospitals reclassified for the wage index beginning during FY 2003. In addition, 367 hospitals are reclassified for FY 2003 based on their 3-year reclassification that became effective during FY 2001, and 181 hospitals are reclassified for FY 2003 based on their 3-year reclassification that became effective during FY 2002. There are 24 hospitals included in the 3-year reclassification from FY 2001 that were reclassified in accordance with section 152(b) of Public Law 106-113. In addition, there are 34 rural hospitals redesignated to an urban area under section 1886(d)(8)(B) of the Act, and 14 urban hospitals that have been designated rural in accordance with section 1886(d)(8)(E) of the Act. Finally, there are 59 hospitals reclassified by the MGCRB for the standardized amount for FY 2003 (including one hospital that is also redesignated under section 1886(d)(8)(B) of the Act to a different MSA). The final FY 2003 wage index values incorporate all of these hospitals. Since publication of the May 9 proposed rule, the number of reclassifications has changed because some MGCRB decisions were still under review by the Administrator and because some hospitals decided to withdraw their requests for reclassification.

Applications for FY 2004 reclassifications are due to the MGCRB by September 3, 2002. We note this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under § 412.273(d) (as added by this final rule). At the time of publication the May 9, 2002 proposed rule, the internet site for reclassification (<http://www.hcfa.gov/regs/mgcrbinfo.htm>) was not operational. To obtain an application for MGCRB reclassification, call the MGCRB at (410) 786-1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670.

Changes to the wage index that resulted from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process have

been incorporated into the wage index values published in this final rule. The changes may affect not only the wage index value for specific geographic areas, but also the wage index value redesignated hospitals receive; that is, whether they receive the wage index value for the area to which they are redesignated, or a wage index value that includes the data for both the hospitals already in the area and the redesignated hospitals. Further, the wage index value for the area from which the hospitals are redesignated may be affected.

In the May 9, 2002 proposed rule, we proposed limited changes and clarifications to the policies related to withdrawals, terminations, and cancellations of the 3-year wage index reclassifications. These are discussed in section V. of this preamble, including any comments received and our responses to those comments.

We receive several comments pertaining to the FY 2003 or FY 2004 MGCRB reclassification process. These are addressed below.

Comment: One commenter expressed concern that the methodology used for wage index reclassification for FY 2003 reclassification applications does not include a process by which corrections to 1996 and 1997 cost reporting data may be submitted. The commenter suggested that we allow for the correction of inaccurate data from prior years as part of a hospital's bid for geographic reclassification, and that not to allow corrections to the data results in inequities in the calculation in the average hourly wage for purposes of reclassification.

Response: Effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act provides that the MGCRB must use the average of the 3 most recent years of hourly wage data for the hospital when evaluating a hospital's request for reclassification. To evaluate applications for wage index reclassifications for FY 2003, the MGCRB used the 3-year average hourly wages published in Table 2 of the August 1, 2001 **Federal Register**. These average hourly wages are taken from data used to calculate the wage indexes for FY 2000, FY 2001, and FY 2002, based on cost reporting periods beginning during FY 1996, FY 1997, and FY 1998, respectively.

In the August 1, 2001 **Federal Register**, we revised the Medicare regulations at § 412.230(e)(2)(ii)(A) to specify that hospitals seeking reclassification must provide a 3-year average hourly wage using data from the hospital wage survey used to construct the wage index in effect for prospective payment purposes (66 FR 39934).

Hospitals have ample opportunity to verify the accuracy of the wage data used to calculate their wage index and to request revisions, but must do so within the prescribed timelines. We consistently instruct hospitals that they are responsible for reviewing their data and availing themselves to the opportunity to correct their wage data within the prescribed timeframes. Once the data are finalized and the wage indexes published in the final rule, they may not be revised, except through the mid-year correction process set forth in the regulations at § 412.63(x)(2). Accordingly, it has been our consistent policy that if a hospital does not request corrections within the prescribed timeframes for the development of the wage index, the hospital may not later seek to revise its data in an attempt to qualify for MGCRB reclassification.

Allowing hospitals the opportunity to revise their data beyond the timelines required to finalize the data used to calculate the wage index each year would lessen the importance of complying with those deadlines. The likely result would be that the data used to compute the wage index would not be as carefully scrutinized because hospitals would know they may change it later, leading to inaccuracy in the data and less stability in the wage indexes from year to year.

Comment: Several commenters requested that we clarify whether we intend to utilize OMB's new MSA standards and, if so, how we intend to incorporate the changes into the Medicare program. Relatedly, one commenter requested that we specify in the text of the final rule whether or not a hospital that was treated as a rural referral center (RRC) as of October 1, 2000, will continue to qualify for the RRC exception if their physical location becomes urban as a result of subsequent updates to metropolitan areas issued by the OMB. The commenter is concerned that the absence of a clear statement in the regulations text indicating that the grandfathered status of RRCs will continue into subsequent years could possibly result in a loss of their special status. The commenter referenced the instance when many RRCs located in areas that were redesignated as urban by OMB lost their RRC status. (See the August 29, 1997 final rule (62 FR 45999) for a more detailed explanation.)

Response: At this time, it is our understanding that OMB is not expected to announce changes to the new MSA standards until after we have published the proposed rule for FY 2004. Even if the new standards are announced in advance of the publication of our FY 2004 proposed rule, we would need

time to assess their implications for payment purposes (for example, how will the new Metropolitan Areas designated by OMB, which will encompass counties currently considered rural, interact with other statutory and regulatory requirements for special hospital designation, such as an RRC).

Therefore, we intend at this time to continue to use the current MSA standards for FY 2004 acute inpatient prospective payment system payments. Hospitals applying for MGCRB reclassification for FY 2004 must apply based on the existing MSA definitions. With respect to the commenter's concern regarding the implications of the revised MSA definitions on RRCs, we are not prepared at this time to address this issue. We intend to evaluate this and other issues related to the new MSA definitions when they become available next year.

Comment: One commenter requested clarification as to whether Table 9, Hospital Reclassifications and Redesignations by Individual Hospital, is an official list and whether the wage index calculation is affected by errors in omission. The commenter indicated that the list in the proposed rule includes hospitals that have withdrawn their FY 2002 reclassifications and subsequently cancelled the withdrawal for FY 2003 and FY 2004, as well as omits hospitals that have received approval letters from the MGCRB reinstating the remaining years of the 3-year appeal.

Response: We indicated in the proposed rule that, while Table 9 shows hospitals that have been reclassified under either section 1886(d)(8)(B) or section 1886(d)(10)(D) of the Act, it may not reflect all withdrawals from reclassifications approved by the MGCRB or decisions of the CMS Administrator if those withdrawals were made subsequent to the preparation of the proposed rule. Similar to the other provisions and tables included in the proposed rule, publication of Table 9 in the proposed rule provided an opportunity for affected hospitals to review and verify the accuracy of the data. In situations such as those described by the commenter, we encourage affected providers to furnish us with specific feedback regarding the information contained in the proposed rule. Any changes that result from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process are incorporated into the wage index values and Table 9 published in the final rule.

Comment: Several commenters requested that the wage data for urban

hospitals redesignated as rural under section 1886(d)(8)(E) of the Act, be included both in the MSA where the hospital is physically located and the rural area to which they are redesignated for purposes of the wage index. Commenters cited section 1886(d)(8) of the Act and section 152(b) of the Balanced Budget Refinement Act of 1999 (Pub. L. 106-113) in support of their request. The commenters asserted that section 1886(d)(8) of the Act protects nonreclassified hospitals from being negatively impacted by reclassifications. They also pointed out that in implementing the statutory reclassifications required by section 152(b) of Public Law 106-113, CMS calculated the wage index values of the MSAs that contain the counties specified in section 152(b) by "including the wages of hospitals that were reclassified out of the MSA by section 152(b)." The commenters stated that the exclusion of hospitals redesignated under section 1886(d)(8)(E) of the Act in calculating the wage index is contrary to the expectations of the hospitals prior to the enactment of this provision (by section 401 of Public Law 106-113).

Response: Section 1886(d)(8)(E) of the Act permits an urban hospital to apply to the Secretary to be treated as being located in the rural area of the State in which the hospital is located. A hospital granted redesignation under section 1886(d)(8)(E) of the Act is therefore treated as a rural hospital for all purposes of payment under the Medicare acute inpatient prospective payment system, including standardized amount, wage index, and disproportionate share calculations, as of the effective date of the redesignation. Therefore, for purposes of calculating the wage index as a result of the redesignation to a rural area, the wage index data of the redesignated hospital is treated as though the hospital were located in the rural area of the State. That is, its data are excluded from the wage index calculation for the urban area where the hospital is geographically located and included in the wage index calculation for the rural area to which the hospital is designated. This is consistent with the statutory language requiring that a hospital be treated as though it is located in a rural area.

In the case of section 1886(d)(8) of the Act, Congress specifically acted to provide special protection for rural hospitals negatively impacted by reclassifications. Section 1886(d)(8)(C) of the Act provides that rural areas are held harmless for decisions resulting from the application of section

1886(d)(8)(B) of the Act, or of decisions of the MGCRB or the Secretary. Redesignations under section 1886(d)(8)(E) of the Act are not covered under this provision.

In the case of section 152(b) of Public Law 106–113, Congress specifically directed the Secretary to treat these statutorily mandated reclassifications as decisions by the MGCRB. Section 1886(d)(8)(E) of the Act directs the Secretary to treat the redesignated hospitals as being located in the rural area of the State in which the hospital is located. We did not exclude the wages of the hospitals reclassified under section 152(b) in calculating the FY 2001 wage index for the affected areas because we believed that this approach appropriately reflected the expectations of the hospitals that had applied to reclassify into the areas affected by this provision prior to enactment of this provision. Because section 1886(d)(8)(E) of the Act has been in place for well

over a year, hospitals applying for reclassification for FY 2003 could not reasonably have expected, in light of the language of that section, that they would benefit from the inclusion of the wage data of the redesignated hospitals in two different areas.

We note that the commenters' suggestion would not uniformly benefit hospitals remaining in or reclassified into the urban area from which the now rural hospital was reclassified. Our analysis indicates several such areas would be negatively impacted. The greatest positive impact would occur in the area of concern to the commenter.

3. OMB Standards for Hospitals to Qualify for Redesignation

In the August 1, 2001 final rule, we implemented section 402 of Public Law 106–113. Section 402 provided that hospitals could elect whether to apply standards developed by OMB in 1980 or 1990 in order to qualify for redesignation under section

1886(d)(8)(B) of the Act. However, section 402 also states that, beginning with FY 2003, hospitals will be required to use the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census.

At this time, the 1990 standards are the most recent available. Although OMB is working to develop updated standards based on the 2000 census, that work is not yet completed. For purposes of redesignation for FY 2003 under section 1886(d)(8)(B) of the Act, qualifying hospitals must be located in counties meeting the 1990 standards.

In the August 1, 2001 final rule, we determined that three counties that qualified for redesignation under the 1980 standards qualified for redesignation to a different MSA using the 1990 standards (66 FR 39869). These counties, which will be redesignated to the MSA to which they qualify based on the 1990 standards, are as follows:

Rural county	1980 MSA designation	1990 MSA designation
Ionia, MI	Lansing-East Lansing, MI	Grand Rapids-Muskegon-Holland, MI.
Caswell, NC	Danville, VA	Greensboro-Winston Salem-High Point, NC.
Harnett, NC	Fayetteville, NC	Raleigh-Durham-Chapel Hill, NC.

Section 402 of Public Law 106–113 amended section 1886(d)(8)(B) of the Act by adding clause (ii). This clause allowed hospitals to elect to use either the January 3, 1980 standards or March 30, 1990 standards for payments during FY 2001 and FY 2002. Several hospitals in counties that did not qualify for redesignation under the January 3, 1980 standards elected to use those older standards so they would not receive the urban designation accorded to them under section 402 because they would lose their special rural designation (that is, an RRC, a sole community hospital (SCH), or a Medicare-dependent hospital (MDH)). Under section 1886(d)(8)(B)(ii) of the Act, the option to make such an election was available only for FY 2001 and FY 2002. Effective for FY 2003, as we proposed, we are providing that hospitals located in counties qualifying for redesignation under section 1886(d)(8)(B) of the Act based on the 1990 standards will be redesignated under this provision.

We also noted in the August 1, 2001 final rule that five rural counties no longer meet the qualifying criteria when we apply the 1990 OMB standards (66 FR 39870). These rural counties are as follows: Indian River, FL; Mason, IL; Owen, IN; Morrow, OH; and Lincoln, WV. Therefore, beginning FY 2003, hospitals in these counties will not be

eligible for redesignation under section 1886(d)(8)(B) of the Act unless the counties again qualify when the standards based on the 2000 census data are available.

Comment: One commenter expressed concern that the reclassification based on 1990 standards disadvantages hospitals classified as RRCs, SCHs, or MDHs by taking away their special status classification because they are no longer considered rural. The commenter was concerned that the provision is not in keeping with Congressional intent. As an alternative, the commenter suggested that an affected hospital should be allowed to request reclassification as a rural hospital under § 412.103(a)(3), which allows hospitals to be treated as rural if they qualify as either a rural referral center or a SCH.

Response: Because the law does not provide for an election on the part of the hospital for FY 2003, while specifying such an election for FYs 2001 and 2002, hospitals in affected counties are reclassified as urban. Therefore, consistent with our longstanding policy that hospitals reclassified as urban for purposes of the standardized amount are considered urban and lose their eligibility for special rural hospital status, the commenter is correct that a hospital becoming urban under section 1886(d)(8)(B)(ii)(II) of the Act would

lose its special status as a result. With respect to the commenter's request that, in the event an affected hospital is not permitted the option to decline reclassification to an urban area that it may apply to be redesignated rural under § 412.103, we agree with the commenter that a reclassified hospital may seek rural redesignation under § 412.103. We will then determine whether the hospital meets the criteria for reclassification under this regulation. However, any such reclassification would be subject to the limitations on reclassification at § 412.230(a)(5)(iv), which prohibit a hospital that has been granted redesignation as a rural hospital under § 412.103 from receiving an additional reclassification by the MGCRB.

We also note that it has been brought to our attention that the reclassifications applicable under section 1886(d)(8)(B)(ii) of the Act are applicable for cost reporting periods beginning in the relevant Federal fiscal year. Therefore, in applying such reclassifications for FY 2003, they are effective as of the beginning of the hospital's cost reporting period beginning during FY 2003. This effective date has no impact on hospitals that are reclassified to the same MSA under this provision as they were reclassified into for FY 2002. Such

hospitals will be paid in accordance with the FY 2003 wage index value of the area to which they are reclassified effective with discharges on or after October 1, 2002. However, hospitals whose reclassification changes as a result of applying the 1990 standards for FY 2003 will be paid in accordance with the wage index applicable to the area to which they would otherwise have been classified were it not for section 1886(d)(8)(B)(ii) of the Act at the start of FY 2003. Then, for discharges occurring on or after the date of the start of their cost reporting period beginning during FY 2003, they will be paid in accordance with the wage index applicable to the area they are reclassified into under section 1886(d)(8)(B)(ii).

G. Requests for Wage Data Corrections

In the May 9, 2002 proposed rule, we stated that, to allow hospitals time to construct the proposed FY 2003 hospital wage index, in May 2002 we would make available a final public data file containing the FY 1999 hospital wage data.

The final wage data file was released on May 10, 2002. As noted above in section III.D. of this preamble, this file included hospitals' cost report data obtained from Worksheet S-3, Parts II and III of their FHY 1999 Medicare cost reports. In addition, Table 2 in the Addendum to this final rule contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 1999 data used to construct the final FY 2003 wage index.

In a memorandum dated December 19, 2001, we instructed all Medicare intermediaries to inform the prospective payment hospitals they service of the availability of the wage data file and the process and timeframe for requesting revisions. The wage data file was made available on January 12, 2002, through the Internet at CMS's home page (<http://www.hcfa.gov>). We also instructed the intermediaries to advise hospitals of the availability of these data either through their representative hospital organizations or directly from CMS. Additional details on ordering this data file were discussed in section IX.A. of the preamble of the May 9, 2002 proposed rule, "Requests for Data from the Public."

In addition, Table 2 in the Addendum to the proposed rule contained each hospital's adjusted average hourly wage used to construct the proposed wage index values for the past 3 years, including the FY 1999 data used to construct the proposed FY 2003 wage index. We noted that the hospital

average hourly wages shown in Table 2 only reflected changes made to a hospital's data and transmitted to CMS prior to February 15, 2002. Changes approved by a hospital's fiscal intermediary and forwarded to CMS by April 5, 2002, were reflected in the final public use wage data file made available on May 10, 2002.

We believe hospitals had sufficient time to ensure the accuracy of their FY 1999 wage data. Moreover, the ultimate responsibility for accurately completing the cost report rests with the hospital, which must attest to the accuracy of the data at the time the cost report is filed. Hospitals should know what wage data were submitted on their cost reports. In addition, they were notified of any changes to their data as a result of their fiscal intermediary's review. However, if a hospital believed that its FY 1999 wage data were incorrectly reported, the hospital was provided an opportunity to submit corrections along with complete, detailed supporting documentation to its intermediary by February 8, 2002.

After reviewing requested changes submitted by hospitals, fiscal intermediaries transmitted any revised cost reports to CMS and forwarded a copy of the revised Worksheet S-3, Parts II and III to the hospitals. In addition, fiscal intermediaries notified hospitals of the changes or the reasons that changes were not accepted. This procedure ensures that hospitals have every opportunity to verify the data that will be used to construct their wage index values. We believe that fiscal intermediaries are generally in the best position to make evaluations regarding the appropriateness of a particular cost and whether it should be included in the wage index data. However, if a hospital disagrees with the fiscal intermediary's resolution of a policy issue (whether a general category of cost is allowable in the wage data), the hospital may contact CMS in an effort to resolve policy disputes. We noted that the April 5, 2002 deadline also applied to these requested changes. During this review, we did not consider issues such as the adequacy of a hospital's supporting documentation, as these types of issues should have been resolved earlier in the process.

These deadlines were necessary to allow sufficient time to review and process the data so that the final wage index calculation could be completed for development of the final FY 2003 prospective payment rates published in this final rule.

We have created the process described above to resolve all substantive wage data correction disputes before we finalize the wage

data for the FY 2003 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above were not afforded a later opportunity to submit wage data corrections or to dispute the intermediary's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above are not permitted to challenge later, before the Provider Reimbursement Review Board, CMS's failure to make a requested data revision (See *W. A. Foote Memorial Hospital v. Shalala*, No. 99-CV-75202-DT (E.D. Mich. 2001)).

As stated above, the final wage data public use file was released on May 10, 2002. Hospitals had an opportunity to examine both Table 2 of the proposed rule and the May 2002 final public use wage data file (which reflected revisions to the data used to calculate the values in Table 2) to verify the data CMS used to calculate the wage index.

As with the file made available in January 2002, CMS made the final wage data file released in May 2002 available to hospital associations and the public on the Internet. However, the May 2002 public use file was made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary in the entry of the final wage data that result from the correction process described above (with the February 8 deadline). Hospitals were encouraged to review their hospital wage data promptly after the release of the May 2002 file. Data presented at that time could not be used by hospitals to initiate new wage data correction requests.

If, after reviewing the May 2002 final file, a hospital believed that its wage data were incorrect due to a fiscal intermediary or CMS error in the entry or tabulation of the final wage data, it was provided an opportunity to send a letter to both its fiscal intermediary and CMS, outlining why the hospital believed an error existed and providing all supporting information, including relevant dates (for example, when it first became aware of the error). These requests had to be received by CMS and the fiscal intermediaries no later than June 7, 2002.

Changes to the hospital wage data were only made in those very limited situations involving an error by the intermediary or CMS that the hospital could not have known about before its review of the final wage data file. Specifically, at this stage of the process, neither the intermediary nor CMS accepted the following types of requests:

- Requests for wage data corrections that were submitted too late to be